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Appendices

Program Description

Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

Animal Research Facility (AF) (VA (b)(6) Research and Development Program Edith Nourse Rogers Veterans Memorial Hospital 200 Springs Road Bedford, MA 01730

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

The Edith Nourse Rogers Memorial Veterans Hospital serves as a major Extended Care facility for veterans residing in the New England Region. As a component of their mission, there are two units within the institution that conduct basic research involving animal experimentation. The Geriatric Research, Education and Clinical Center (GRECC) and the Research Service are closely allied units having major research projects in neurosciences and immunology. These research groups, especially those in neurosciences, are involved in studies of neurological disease states, which primarily utilize mice as the most appropriate animal model. These areas are particularly relevant to this institution since a significant portion of the patient population suffers from chronic neurological disabilities. The Animal Research Facility is organizationally located under Research Services.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act

regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

This institution utilizes the Guide for the Care and Use of Laboratory Animals, Public Health Service (PHS) Policy, and U.S. Department of Agriculture (USDA), standards for the animal care and use program. It has established and maintained proper measures to ensure appropriate care and use of all animals involved in research, research training, and biological testing activities. The primary functions of the staff of the Animal Research Facility are:

(1) To provide optimum care and husbandry to the laboratory animal colonies;
(2) To ensure compliance with all local, state and federal laws and regulations pertaining to laboratory animal research.

This is done in such a manner so as to ensure effective and humane utilization of laboratory animals, maintain a high-quality animal care program, and minimize interference in the research protocol.

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

The Edith Nourse Rogers Memorial Veterans Hospital serves as a major Extended Care facility for veterans residing in the New England Region. As a component of their mission, two units within the institution conduct basic research involving animal experimentation. The Geriatric Research, Education and Clinical Center (GRECC) and the Research Service are closely allied units having major research projects in neurosciences, and immunology. These research groups, especially those in neurosciences, are involved in studies of neurological disease states, which primarily utilize mice as the most appropriate animal model. These areas are particularly relevant to this institution since a significant portion of the patient population suffers from chronic neurological disabilities.

The Animal Research Facility (ARF) is a (b)(6) (b)(6) Rooms are available for animal housing, breeding, quarantine, procedures, feed/bedding storage, cage wash, equipment storage, office, lounge and toilet/shower. Building (b)(6) also houses other research laboratories, common equipment rooms, and offices for investigators and administrative staff.

Supervision of the Animal Facility extends from the Medical Center Director, Ms. Joan Clifford, through the Chief Medical Officer, Dr. Daniel Berlowitz, to the Acting Associate Chief of Staff for Research and Development (ACOS/R&D) (b)(6) and the Administrative Officer (b)(6) to the part-time VMO, Dr. William Webster, to the Animal Facility Supervisor, (b)(6) who is responsible for the daily activities of the facility. The Institutional Animal Care and Use Committee (IACUC) maintains oversight of the animal care program, in accord with all applicable Federal regulations and nationally recognized guidelines, and with specific responsibility for review of all animal research protocols as well as semi-annual program reviews.

See Appendix 1

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

Joan Clifford, DNP, Institutional Official
William Webster, D.V.M., MS, PhD, Veterinary Medical Officer
Peter Morin, MD, PhD, Chair, IACUC
(b)(6) Interim Associate Chief of Staff/Research and Development Program
(b)(6) Administrative Officer/ Research and Development Program
(b)(6), ARF Supervisor
(b)(6) Chief, Safety, Safety Manager/Industrial Hygienist
(b)(6), Radiation Safety Officer and Research Biosafety Officer

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The major type of research performed in the Animal Research Facility is in neuroscience. There are currently 3 active protocols. One investigator has an approved experimental animal protocol, and there are 2 supportive protocols to provide for the use of sentinel animals in facility disease surveillance, and to provide for the temporary holding of investigator animals. There are no teaching programs associated with this facility.

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Department of Veteran Affairs, VA Merit Research awards and VA Research General Post Funds (donations).

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

There are no other units of this organization that house and use animals.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

This institution does not contract for animal care facilities or services.

J. Note other relevant background that will assist reviewers of this report.

None

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

Any program needs discussed by the IACUC and Attending Veterinarian are included in the IACUC meeting minutes, which are submitted to the Medical Center Director. In addition, IACUC members meet with the Medical Center Director twice a year to discuss the semi-annual program review conducted by the IACUC. This contact provides an opportunity to communicate program needs. If an urgent program need were to arise in the interim, the Medical Center Director would be notified immediately through the IACUC chair and ACOS/R&D.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.
  Note: If preferred, this information may be provided in a Table or additional Appendix.

William Webster, D.V.M., MS, PhD, DACLAM is the part-time Veterinary Medical Officer (VMO). He regularly visits and inspects the animal facility on a bi-weekly basis, handles animal health issues, meets with the ARF Supervisor regarding operations, attends IACUC meetings, and provides formal and informal training to animal users and the IACUC. He is also available for any emergency veterinary issues that may arise on evenings, weekends, or holidays.

His responsibilities include overseeing and monitoring the following:

1) Disease detection and surveillance, prevention, diagnosis, treatment, and resolution
2) Handling and restraint; anesthetics, analgesics and tranquilizer drugs; and methods of euthanasia
3) Surgical and post-surgical care
4) Promotion and monitoring of animal's physical and psychological well-being
5) Adequacy of the husbandry program
6) Review and approval of all animal care and use, e.g., via a role on the IACUC
7) Training of institutional staff in the care and use of laboratory animals
8) Assistance in establishment and/or monitoring of the Occupational Health Program
9) Monitoring for zoonotic diseases
10) Advising on and monitoring biohazard control policies and procedures relevant to the animal care and use program

(b)(6) acts as a backup veterinarian for the facility when Dr. Webster is unavailable. (b)(6) is Attending Veterinarian at the (b)(6)

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.

Note: If preferred, this information may be provided in a Table or additional Appendix.

The Animal Research Facility Supervisor monitors the physical plant/environment, health, and care of the animals on a daily basis. The Supervisor performs health surveillance via sentinel mice and veterinary treatments, as assigned by the Veterinarian.

c. Interinstitutional Collaborations [*Guide*, p. 15]

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

There are no off-site locations/collaborations.

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.

Note: Do not include details about the training program, which should be described in the following sections.

There are several programs in place to ensure adequate personnel training. All aspects of the animal care and use program are reviewed semi-annually by the IACUC as part of the required Semi-annual Program Review. Training for IACUC members is provided at committee meetings, as by discussion of CVMO-provided training scenarios, and is documented in the minutes. The VMO provides CE by way of updates and relevant training on current topics in laboratory animal use and care, at committee meetings. He also provides training in the humane care of laboratory animals for new employees, and for all staff as needed, in a Power Point presentation entitled "Animal Care and Use Practices." IACUC members, Investigators, Research Technicians, and animal facility staff are also required to complete all CITI training pertinent to their role in the institution, as well as research-specific and mandatory Bedford VA Hospital training. For example, all animal care and research staff must complete the CITI Module on "Working with Mice in Research Settings", and all IACUC members must complete the module entitled "Essentials for IACUC Members." All Investigators and their staff must complete all required training before they may commence work and must remain in compliance. Principal investigators maintain a written scope of work for each member of their research team and develop a corresponding training checklist/certification of required trainings needed to perform assigned duties. Investigators certify that members of their research team have received appropriate training to perform the duties assigned. At the time of continuing review of an ACORP, investigators certify each individual's scope of work and training checklist.
Attendance at relevant regional and national educational meetings, such as NEBAALAS, National AALAS and IACUC 101, is encouraged.

The Research Office maintains a record of completed training in a training database. It monitors training compliance monthly, and also verifies training status when Investigators submit annual reviews or 3-year renewals of their ACORP

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

William Webster, D.V.M., MS, PhD, DACLAM
(b)(6)

(b)(6)

Continuing education is completed as needed, to meet ACLAM recertification requirements, for veterinary medical license renewal and to remain current in the field.

ii. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

1 full-time

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.
Note: If preferred, this information may be provided in a Table or additional Appendix.

(b)(6) ARF Supervisor. (b)(6)
(b)(6)

All staff receive video training in the humane handling and care of lab animals, by the ARF Supervisor.
The ARF supervisor also provides hands-on training in the proper handling and care of lab animals. The VA provides occupational health and safety training, as well as opportunities to attend laboratory animal seminars, short courses or research lectures. The Bedford VAMC is also enrolled in the AALAS Learning Library and CITI, which provides online access to staff members interested in obtaining additional education and required training. The mouse husbandry and care module review is required training for animal care staff and research technicians, while the VA IACUC module review is

required training for IACUC members. The rat husbandry and care module review would be required if and when rats were to be utilized in a protocol.

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

Principal investigators have open access to the veterinarian for information regarding particular protocols or procedures. Being a small facility, personnel who have animal contact are usually present at IACUC meetings, where maximum interaction and exchange of information occurs. Research staff are required every three years, to complete the CITI training course "Working with Mice in Research Settings". The IACUC also discusses training scenarios/modules provided by the CVMO on a frequent basis, as another means of providing continuing education for members. Training is a continual process.

The research technicians are given instruction in the proper care and treatment of animals by the investigator in charge of that particular research protocol or project. They have access to the VMO should procedural questions arise. In addition, they are monitored and instructed by the supervisor of the animal care facility, and their animal procedures are subject to periodic Post Approval Monitoring (PAM) conducted by the VMO.

New employees are required to view a training video on humane care, animal handling, and methodologies. The video is available in the animal research facility. Each new employee meets with the Veterinarian, and he provides training pertinent to the procedures proposed, including animal care, restraint, anesthesia, analgesia, and humane practices.

a) Briefly describe the content of any required training.

The species-specific CITI training course includes modules such as Injections, Blood Collection, Antibody Production, Pain Relief, Surgery, Supportive Care and Monitoring, Detecting Pain and Distress, Genetics and Biological Features, and Euthanasia. The video on humane care and handling of animals includes topics such as injections, blood collection, restraint, and proper PPE. All animal users must participate in training by the VMO, on the Power Point Presentation on "Animal Care and Use Practices".

b) Describe the timing of training requirements relative to the commencement of work.

Researchers and their staff must have completed all required Research-specific training prior to commencement of work. In addition, they must remain up to date on required training to continue work. The PI must ensure their research staff are properly trained in performing procedures prior to commencing work.

c) Describe continuing education opportunities offered.

Individuals involved in animal experimentation are given the opportunity to attend relevant symposia, seminars, or lectures that apply to important current issues in animal treatment and care. Examples would be the IACUC 101 courses and the annual PRIMR conferences. Continuing education is also available through the VA's subscription to the AAALAS Learning Library.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures.
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

No surgeries are currently being performed. The investigator would meet with the VMO prior to protocol submission to the IACUC to ensure the persons performing procedures are properly trained. For surgical protocols, staff would be required to provide a detailed outline of their surgical and animal experience as part of the protocol application. Staff who are not experienced with a particular species or procedure would be trained by the Investigator and/or the Veterinarian. Staff performing procedures are monitored as part of the Post Approval Monitoring Program.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

The investigator meets with the VMO prior to protocol submission to ensure the persons performing procedures are properly trained. For surgical protocols, staff would be required to provide a detailed outline of their surgical and animal experience as part of the protocol application. Staff who are not experienced with anesthesia would be trained by the Investigator and/or the Veterinarian. Staff performing anesthesia are monitored as part of the Post Approval Monitoring Program.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

Investigators are required to provide a detailed outline of their staff's experience as part of the protocol application. Staff who are not experienced with euthanasia procedures would be trained by the Investigator and/or the Veterinarian. Staff performing euthanasia are monitored as part of the Post Approval Monitoring Program. The ARF Supervisor also monitors new or inexperienced staff to ensure euthanasia is performed properly.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g., remote offices to which personnel must report).

The program is established in accordance with the Department of Veterans Affairs VHA Handbook 1200.7 "Use of Animals in Research", section 10 "Occupational Health and Safety". All staff who work with animals are enrolled in the Occupational Health and Safety program, which is operated by the Occupational Health Service (OHS). OHS is responsible for administration and oversight of the program. They are also responsible for the medical aspects of the program, including maintenance of medical records. Staff is defined as "personnel who are involved in the direct care of animals and their living quarters and have direct contact with animals (live or dead), their viable tissues, body fluids, or wastes". Proposed animal studies that would involve the use of potentially hazardous agents are identified at the time of protocol review by the IACUC. The investigator must respond to questions on the ACORP pertaining to radioisotope use, infectious agents and other biohazards. Safety concerns regarding the use of these agents are addressed by the Subcommittee for

Research Safety (SRS). The IACUC does not approve animal protocols involving hazardous agents until they are approved by the SRS.

The Safety Manager is a member of the Subcommittee for Research Safety (SRS), and reviews protocols for potential safety issues.

Principal Investigators are responsible for ensuring employee education and documentation of training in occupational health and safety issues, including animal allergy, zoonoses and hazardous substances. The VMO informs personnel about zoonoses and special precautionary actions to be taken relative to continuous exposure to laboratory animals and their wastes.

The Research Office monitors compliance of staff with all research-required training. Annual online Hazard Communication training and Blood borne Pathogens training is required for all employees who may potentially be exposed to hazardous agents.

The IACUC Coordinator provides OHS a list of Research Service employees assigned/requiring access to the Animal Research Facility. The IACUC receives communications from OHS, through the IACUC Coordinator, to assist in monitoring the status of employees. OHS will notify the IACUC Coordinator of any employees whose required annual occupational health evaluations have lapsed.

Engineering Service and Facilities Management Service provide OHS with names of individuals having episodic contact with the Animal Research Facility. Surveillance and screening of these individuals for potential work related hazards is provided by OHS.

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

Personnel are categorized according to occupational risk (high, moderate, low). The assessment of risk is determined by frequency of animal contact, intensity of exposure, hazards associated with the animals being handled, hazardous properties of agents used in research, the susceptibility of individual employees, the hazard control measures available and the occupational history

of individual employees. Individuals in the highest risk category may require additional pre-employment workup.

Occupational health services are available to all VA employees who work in Research and have direct animal contact, as well as support staff involved in the animal care and use program who access the animal facility. Individuals having episodic contact with the Animal Research Facility, such as Engineering and Facilities Management staff, participate in the program as well.

The IACUC SOP "Animal Facility Access" describes three different levels of access to the facility based on occupation. Level 1 describes access procedures required for investigators, technicians, and ARF personnel. Level 2 procedures apply to non-research VA personnel, i.e. individuals that must require access to the animal facility to fulfill their regulatory, maintenance, housekeeping, safety or law enforcement duties. Level 3 applies to visitors, vendors, and students.

Annual online Hazard Communication training and Blood borne Pathogens training is required for all employees who may potentially be exposed to hazardous agents.

Identification of all known hazards is required by the IACUC and must be included in the ACORP submission. As part of the IACUC review process, the Subcommittee for Research Safety (SRS) also reviews protocols to ensure that potential risks are appropriately assessed, and safeguards are included. IACUC approval is withheld until safety approval is granted. Safeguards are selected based on published regulations and recommendations, as well as professional knowledge of the Safety Manager and any requirements of the Investigator. OHS is notified of all infectious agents being studied and when animals may carry a zoonotic disease. Professional experts on specific infectious agents may also be consulted.

The IACUC policy, "Zoonoses and Personnel Protection" describes potential risks to personnel, and the various risk levels. Each employee is required to complete the ENRM VA Hospital Occupational Health Service "Periodic Animal Exposure Questionnaire" annually, which evaluates potential risks and determines level of risk applicable to their work environment. Employees contracting allergies to animals during their tenure of employment are referred to OHS. Preventive measures such as masks and fit-tested respirators may be provided if necessary.

3) Describe methods and frequency of reassessing work-related hazards.

Each employee is required to complete the ENRM VA Hospital Occupational Health Service "Periodic Animal Exposure Questionnaire" annually, which evaluates potential risks and determines level of risk applicable to their work environment. Employees contracting allergies to animals during their tenure of employment are referred to OHS.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

In the event that there is an incident, accident or injury to personnel related to anim.al care or use, the employee will report to OHS for evaluation. The event will be entered in the hospital's ECOMP injury tracking system (formerly ASISTS) and reported to the SRS. The Principal Investigator/ supervisor will be notified by the employee to investigate and provide recommendation for corrective action

Accidents in the animal facility and bite wounds are to be reported to the ARF Supervisor, who will refer the individual to the Occupational Health Service for care. Exposure to chemicals, radioisotopes or infectious agents is reported to the Safety Office and/or the Radiation Safety Officer, and Occupational Health Service.

Per VHA Handbook 1058.01, within 5 days of becoming aware of any apparent work-related exposure of VA research personnel (or apparent research-related exposure of any other person) to hazardous, toxic, or infectious materials at greater than routine levels (i.e., Permissible Exposure Limits or Infection Threshold) or any exposure or injury that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death, members of the VA research community are required to ensure that the exposure or injury has been reported in writing to the SRS.

The SRS must review at its next convened meeting any report involving such an incident or event. Incidents that present a significant risk to the safety of research personnel or the environment may require immediate attention and result in the need to convene an emergency session of the SRS prior to the next scheduled meeting.

ii. Standard Working Conditions and Baseline Precautions

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection***

iii below.

1) **Medical Evaluation and Preventive Medicine for Personnel** [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

   a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

Personnel categorized as Access level 1 or 2 are required to complete the ENRM VA Hospital Occupational Health Service "Periodic Animal Exposure Questionnaire" annually. Access level 3 individuals are exempted from personal medical evaluation.

   b) Describe provisions for allowing an individual (following completion of individual health and job-related risk assessments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
   Note: Do not include names of the personnel

Item G. "Occupational Health and Safety" on the ACORP form requires the PI to list the type of enrollment in an occupational health and safety program (OHSP) for each of the personnel listed on the protocol. Personnel can be enrolled in the VA program, or an equivalent alternate program. The form also must indicate if the personal declined optional services, and if they are current on interactions with the OHSP. Currently there are no personnel who have declined participation in the medical evaluation program.

   c) Describe provisions for assuring confidentiality of medical information.

Annual allergy questionnaires are submitted in sealed envelopes to the IACUC Coordinator, who forwards them to the OHSP office.

   d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open

laboratories).

Engineering Service and Facilities Management Service provide OHS with names of individuals having episodic contact with the Animal Research Facility. Surveillance and screening of these individuals for potential work related hazards is provided by OHS.

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

All personnel are required to have a physical examination at the Bedford VA prerequisite to employment. This includes research and administrative employees in addition to ARF personnel. The Bedford VA Occupational Health Service (OHS) will maintain all records of employee treatment and care, including tetanus immunizations. Allergy screening questionnaires will be sent directly to OHS to be stored in the employee's file. OHS has eliminated the requirement for routine tuberculin screening tests. Currently only rodents are housed in the Bedford VA animal facility. Animal facility accidents and bite wounds are to be reported to the ARF Supervisor, who will refer the individual to OHS for care. Employees will receive tetanus toxoid boosters at least every 10 years. Other vaccines, e.g., rabies, may be provided based on occupational risk.

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

Currently no other entities provide medical services.

2) Personnel Training Regarding Occupational Health and Safety [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

The Department of Veterans Affairs provides comprehensive occupational health and safety training for all employees through the VA Learning University Talent Management System (TMS) and the Collaborative Institutional Training Initiative program (CITI). Training includes Hazard Communication (Right to Know), Bloodborne Pathogens, Radiation Safety, Supervisor Safety Training, Working with Rats in Research Settings and Working with Mice in Research Settings. Training must be completed prior to work activities.

The Safety Manager also works with individual investigators and their staff when the need arises for particular biohazards.

The VMO informs personnel about zoonoses and special precautionary actions to be taken relative to continuous exposure to laboratory animals and their wastes. In addition, each employee is required to complete a "Periodic Animal Exposure Questionnaire", which informs them of potential risks and determines level of risk applicable to their work environment. The protocol review process has also proven to be effective in alerting research personnel to the hazards of chemical agents used.

Principal Investigators are responsible for ensuring employee education and documentation of training in occupational health and safety issues, including animal allergy, zoonoses and hazardous substances.

The Research Office monitors compliance of staff with all research-required training. Annual online Hazard Communication training and Blood borne

Pathogens training is required for all employees who may potentially be exposed to hazardous agents.

3) **Personal Hygiene** [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Lab coats, scrubs, shoe covers, gloves, disposable dust masks and safety goggles are provided for all ARF personnel.

b) Describe arrangements for laundering work clothing.

Work clothing is laundered in house.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Changing facilities (b)(6) are provided in the ARF for washing hands and changing clothes. A shower is available but not required. Staff change into clean scrubs prior to working in the animal rooms and change out of scrubs at the end of each day. Work clothes are not worn outside the facility.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

The introduction of food and/or beverage into the animal facility is prohibited, except in designated areas. Designated areas are the office and employee break area only. Smoking in the animal facility is prohibited. Smoking at the Bedford VAMC is restricted to designated outdoor smoking areas. The Bedford VAMC is transitioning to a smoke-free environment, to be fully implemented in calendar year 2020.

4) **Standard Personnel Protection** [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

The ARF staff is instructed by the VMO or Supervisor of the ARF on the proper procedures required in handling animals to reduce the risk of physical injury. In addition, equipment such as carts for moving cages and other heavy items, gloves for handling hot cages, and stepladders for reaching heights are provided. The Bedford VA provides a Back Care Training class during employee orientation. Staff also receive training on the proper handling of chemicals, sharps, and other potentially hazardous items during annual Hazard Communication and Bloodborne Pathogens training. The ARF is equipped with an emergency shower and eyewash.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Animal dander and dirty cage bedding are likely sources of allergens. Respirators are currently not required. Dust masks are used in animal rooms, in the cage washing room when dirty cages are emptied in the HEPA-filtered dump station, and when mixing clean bedding for filling clean cages in the storage room.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Zoonotic agents are shed from animals via saliva, feces, urine, and exudative skin lesions. Zoonoses are most effectively avoided by purchasing animals that do not harbor these agents, a policy we endorse. Gloves, and in some cases splash-proof eye protection are used to prevent entry of zoonotic agents into humans. Wearing a facemask when working with animals or animal products minimizes aerosol transmission of disease-producing organisms. Hands are washed before and after handling animals or animal products. No eating, drinking, or smoking is allowed in the animal or treatment rooms. Needles must be disposed of in a puncture-proof container.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

Fume hoods and biological safety cabinets are certified semi-annually through a VA contract with a commercial vendor.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

Respirators are currently not required. Dust masks are used in animal rooms, in the cage washing room when dirty cages are emptied in the HEPA-filtered dump station, and when mixing clean bedding for filling clean cages in the storage room.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

The OHSP provides medical clearance and fit-testing of respirators if needed.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

Respirators are currently not required.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

The animal facility has a Northstar cage washer, but does not have a rack or tunnel washer. A cage washer SOP is attached to the front of the machine detailing proper use of the cage washer. The sole employee in the animal facility has many years' experience operating cage washers.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

No other heavy equipment is used.

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

No motorized vehicles are used for animal transport.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

No medical gases or volatile anesthetics are currently in use.

iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

None

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

None

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

None

2) Experiment-Related Hazard Use [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing

experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

Proposed animal studies that would involve the use of potentially hazardous agents are identified at the time of protocol review by the IACUC. The investigator must respond to questions on the ACORP pertaining to radioisotope use, infectious agents and other biohazards. Safety concerns regarding the use of these agents are addressed by the Subcommittee on Research Safety (SRS). The IACUC does not approve animal protocols involving hazardous agents until they are approved by the SRS.

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

Oversight of animal studies using hazardous agents is provided by the Safety Manager. Radioisotope studies in animals are monitored by the Radiation Safety Officer (RSO). Investigators are responsible for the supervision of their research personnel who work with radioisotopes. Procedures for the handling of radioactive animal bedding, carcasses and caging are outlined in the ACORP prior to approval of the study. The investigator and his/her staff are responsible for the primary handling and disposal of radioactive animals and associated wastes. The RSO is responsible for the storage of radioactive animal carcasses in a dedicated freezer and oversees the disposal/decontamination of materials used in conjunction with animal studies. The RSO performs environmental monitoring for radioactive contamination. Cages are monitored and certified safe before they return to the normal equipment stream.

Studies with infectious agents and recombinant DNA involving animals undergo review by the hospital Safety Manager and the Subcommittee for Research Safety Institutional Biosafety Committee (IBC).

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

No hazardous agents are currently in use. Research personnel involved with the project perform all direct handling of hazardous materials, animals, cages, and wastes. The animal care staff observes the animals on a daily basis.

Safety and decontamination procedures are specified in the hazardous agent protocol. All cages housing animals contaminated with these types of agents must be labeled with special instructions and clearly marked. The Principal Investigator will be responsible for handling the cages during the hazardous period and the ARF staff will only handle the cages after the designated hazardous period has ended. Animal carcasses are stored in the ARF in a dedicated freezer. Sharps are stored in the rooms in which they are used until containers are full. The Bedford VA has a vendor on contract for biweekly removal of hazardous waste from the facility. The vendor is contacted on an as needed basis for removal of waste from the ARF.

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

All new employees are required to complete questionnaires about their medical history of allergies to animals during their pre-employment physical. A complete physical examination, assurance of current tetanus immunization and any other diagnostic or laboratory examinations as indicated by work assignment and type of animal contact, are performed on personnel potentially exposed to hazardous agents. In unusual situations, sera may be banked on those animal care and research personnel who are directly involved with a specific hazardous agent.

3) Hazardous Agent Training for Personnel [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

A specialist in the field is responsible for the training of staff working with specific hazardous agents. The Radiation Safety Officer (RSO) provides training for radioactive hazards. The Hospital Safety Manager provides training and reviews the use of biohazards, chemicals, and toxic hazards in animals. Investigators must ensure that laboratory staff have received the appropriate training and have been observed working with hazardous agents to ensure that proper procedures are being used.

4) Facilities, Equipment and Monitoring [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
Note: If preferred, information may be provided in a Table or additional Appendix.

No hazardous agents are currently in use.

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

No hazardous agents are currently in use.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

No hazardous agents are currently in use.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

No hazardous agents are currently in use.

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

No animal work is being performed in facilities that are used for human-based research or patient areas.

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

Occasionally animals may be transported by carrying covered mouse cages in opaque nylon bags through short common use corridors when animal work in the lab is required. At present, the only external lab is located in the immediately (b)(6) Elevators are not used.

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7.**

i. Describe Committee membership appointment procedures.

The Institutional Animal Care and Use Committee membership is composed of at least five members: a Chair, Veterinarian, Scientist, Non-scientist, and Non-affiliate. The veterinarian must have training or experience in laboratory animal science and medicine and have direct or delegated program responsibility for activities involving animals at the Bedford VA Hospital. At least one member of the committee must have no affiliation with the Bedford VA Hospital. This person may not be part of the immediate family of a person who is affiliated with the medical center. The person chosen provides representation in the IACUC for general community interest in the proper care and treatment of animals. A veteran who volunteers at the medical center is considered to have an affiliation with the institution and is disqualified from serving as the non-affiliated IACUC member; however, appointment of such veterans to the IACUC in another capacity, such as lay member is strongly encouraged. Veterans who do not use a VA medical center for medical care may serve as the non-affiliated member on that medical center's IACUC, as long as they have no other affiliation with the medical center and are not in the immediate family of a medical center employee.

The designation of lay members as both the lay member and the non-affiliated member is discouraged. Recruitment of separate individuals to fulfill these roles is a best practice.

To facilitate communication related to research using laboratory animals within the research administration, it is required that the committee includes at least one member of the research Safety Committee and the Research and Development Committee.

The committee has access to expertise in biostatistics and ethics to provide appropriate consultation as needed. Ethical concerns can be referred to the appropriate Committee within the facility's Integrated Ethics Program (Consultative, Preventative, or Institutional Ethics Committees). The IACUC retains final authority on ethical issues related to the conduct of animal research but may consult appropriate ethical committees as needed.

Members will be appointed by the Medical Center Director for a term of three years subject to renewal. Members may be re-appointed without lapse in service to

the IACUC. Members may be removed from the IACUC by the Medical Center Director for inadequate participation (e.g., poor attendance) or other reasons. The IACUC Chair will be appointed by the Institutional Official for a one-year renewable term.

The Research Compliance Officer is invited at the discretion of the Chair. This position is that of a non-voting consultant and does not add to the quorum.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The IACUC currently meets every other month, or more frequently as needed.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

The IACUC chair provides orientation to new members. Members are provided a copy of the "IACUC Guidebook" as well as the Bedford VA IACUC SOP and policy manual. General training for IACUC members in the appropriate care and use of laboratory animals is provided through the Collaborative Institutional Training Initiative (CITI), and through direct training sessions with the Veterinary Medical Officer. CITI training in IACUC purpose and policies and species-specific training is accomplished by way of web-based courses such as "Essentials for IACUC Members", "Working With the VA IACUC", and "Working With Mice in Research Settings". Additional training is provided periodically at IACUC meetings, by presenting VA-provided IACUC scenarios that enable committee discussion of the situation described in the scenario. Members are also encouraged to attend local PRIMR conferences such as "IACUC 101".

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

All investigators must consult with the VMO in the planning stages of the project at least 10 days prior to submission of the completed "Animal Component of Research Protocol" (ACORP). Verification of the discussion is indicated on the ACORP form. All application material is submitted to Research Administration with enough time to allow for administrative pre-review. Complete protocols are sent to all IACUC members. At the convened IACUC meeting, a quorum of members discusses the ACORP under the full committee review mechanism. A majority vote of a quorum of the committee determines whether the protocol is approved, requires modifications to secure approval, or is disapproved. The approval process is the same for all protocols including pilot studies and internally funded research.

Committee members with self-interest in a proposal are only allowed to provide information on, and cannot vote on, the protocol. Within a week after the meeting, the investigator is notified of the status of his/her ACORP through a "Report of Action" form. Any issues that must be resolved are outlined for protocols that require changes or are disapproved. Prior to full approval, all protocols are reviewed by the Safety Committee and the R&D Committee.

An approved protocol must be renewed annually to remain active. Following its initial approval for year 1, a protocol can be renewed for a second or third year by completion of a "Request for Continued Approval of Animal Use" form. All annual renewals for a given month are listed on the agenda and voted on by the committee. All protocols expire after three years. If the project is to be continued, a new ACORP must be submitted to the IACUC for full review as outlined above.

Protocol amendments are reviewed and approved in the same fashion as the protocols themselves.

Weighing potential adverse effects of the study against the potential benefits
The ACORP form contains questions that require the investigator to describe how the research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for the protocol.

Protocols that have the potential to cause pain or distress
A description of procedures that have the potential to cause pain or distress must include the monitoring method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery, the person responsible for the monitoring, and the method(s) by which pain or distress will be alleviated during or after the procedure. The ACORP form requires the investigator to perform a

database search for alternatives to these procedures and list the sources and key words used.

Veterinary input

Veterinary consultation during the planning of the protocol is required and must be documented on the ACORP form.

The investigator must describe the experimental design for the animal experiments planned, and the sequence of events to reveal what happens to the animals. The description must include all procedures and manipulations and explain why they must be performed.

Use of animals and experimental group sizes

Group sizes, total number of animals requested, and choice of species must be justified. A best estimate must be given of how many animals will undergo the procedures or manipulations described. For complicated experimental designs, a power analysis, flow chart, diagram, or table is strongly recommended to help the IACUC understand what is proposed.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

Any proposed modification to an approved protocol must be approved by the IACUC prior to implementation. This includes, but is not limited to, changes to procedures, housing requirements, pre- or post-operative care, euthanasia, the addition of animals, or the addition or deletion of personnel. Investigators who wish to initiate a change in a protocol must submit an amendment form to the IACUC Coordinator, along with any new or changed pages from the ACORP Appendices. Information on the amendment form should describe in detail the proposed modifications, justification for the proposed changes, and any effects that the modifications may have on the animal(s). Pages from the ACORP should not be submitted unless they contain information that is not presented in ACORP appendices (funding source, personnel, etc.). Minor amendments may be approved by the Chair of the IACUC on an ad-hoc basis. Major amendments are presented to the IACUC for full committee review. The chair may decide that the amendment represents significant procedural changes that require the submission of a new IACUC protocol.

The following are examples of major changes that are to be presented to the entire IACUC. If several significant changes occur, it may warrant submission of a new ACORP.

- A change in the overall aim or objective of the study which supports the need to perform the animal work.
- A change which may involve an increase in the level of pain,

distress, and/or discomfort so as to categorize it in a different USDA category.
- A change from non-surgery to surgery; from minor to major surgery; from non-survival to survival surgery, or from single to multiple survival surgery.
- A large increase in the number of animals to be used.
- The addition of a hazardous agent used in the animal procedure.

The following are examples of minor changes and may be approved by the IACUC Chair after review by the Veterinary Medical Officer.

- A change in the personnel who will be performing procedures involving animals.
- A small increase in the number of animals to be used.
- A minor change in technique that does not change the intent of the ACORP, nor change the level of discomfort, distress, or pain (remains in the same USDA category).
- A change in the dose of an agent that is already approved in the ACORP

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

All ACORP submissions require a description of endpoint criteria, as well as a literature search for alternatives to painful procedures. Investigators are required to provide a list of potentially painful procedures, databases searched, key words, and dates of searches.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

Alternatives to humane endpoints must be described on Appendix 9 of the ACORP. The investigator must describe the specific alternate standard(s) that will be met on the protocol, and how they will be monitored. They must provide the scientific, veterinary medical, or animal welfare considerations that

justify this alternative. Upon veterinary consultation during the planning of the protocol, it may be determined that a pilot study is required.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

The VMO and the Animal Facility Supervisor monitor all animals, biweekly and daily, respectively. The Investigator or his/her staff will check animals for behavior, appetite, and mobility to monitor for pain and distress. Staff are provided VA-required CITI training, as well as training by the investigator that is necessary to perform procedures specific to the protocol. If an animal is determined to be ill, at least daily there must be a date, initials and a brief summary of the health of the animals recorded in a log kept in the animal room. Records will be kept by the Research Staff of daily checks, and must list all supplemental support (heat, fluids, analgesics, antibiotics, etc.) that are provided to animals. These records will indicate the date and time, any problems noted (or note if there have been no changes in the animal's condition). Documentation will be kept from disease onset to endpoint.

ii. Unexpected Outcomes that Affect Animal Well-being [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

Unexpected outcomes would be observed by either the investigator, the ARF Supervisor or the VMO. Both a Mortality Trend Report and Sick Animal Report are standing items on the IACUC agenda. A report is provided by the ARF Supervisor at each IACUC meeting. This enables the IACUC to identify potential issues with experimental procedures. The ACORP form requires that investigators list each group of genetically modified animals and describe for each, any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For newly generated genetic modifications in a protocol, investigators must describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.

iii. Physical Restraint [*Guide*, pp. 29-30]
Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

No protocols use prolonged restraint.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
   - the duration of confinement
   - acclimation procedures
   - monitoring procedures
   - criteria for removing animals that do not adapt or acclimate, and
   - provision of veterinary care for animals with adverse clinical consequences.

   Note: If preferred, this information may be provided in a Table or additional Appendix.

No restraint devices have been used within the last three years.

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]
Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

Recommendations on surgery on research animals in "the Guide", the Public Health Service Policy and USDA regulations (Animal Welfare Act) are followed. These regulatory and guideline documents form the basis within which the Bedford VA IACUC operates. All surgical procedures performed on research animals must be completely described in the ACORP.. While multiple survival surgical procedures on a single animal are strongly discouraged, they may be permitted if scientifically justified and approved by the IACUC.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

   Note: If preferred, this information may be provided in a Table or additional Appendix.

No protocols currently involve multiple major survival surgical procedures.

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

No protocols currently require food or fluid regulation.

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

All drugs and other substances currently used in vivo are of pharmaceutical-grade quality. The investigator must list all materials administered to animals on Appendix 3 of the ACORP. The investigator must give consideration to the grade, sterility, site and route of administration, formulation, compatibility and pharmacokinetics of the NPG substance to be administered. They must explain why the use of a non-pharmaceutical grade formulation is necessary and describe how it will be ensured that the material is suitable for use. A more complete description of NPG substance use is given in the SOP entitled "Use of Non-Pharmaceutical (non-USP) Grade Substances in Animals.

vii. Field Investigations [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

N/A

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

Current policies do not provide for the reuse of individual animals. We currently only have one experimental animal protocol.

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

No protocols involve the reuse of individual animals.

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

There are no instances. No protocols involve the reuse of individual animals.

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

An approved protocol must be renewed annually to remain active. Following its initial approval for year 1, a protocol can be renewed for a second or third year by completion of a "Request for Continued Approval of Animal Use" form. This annual review solicits information regarding the number of animals used in the previous year, whether there have been any changes to the protocol, whether there have been any safety changes associated with the protocol, and whether the protocol is currently active. The investigator must also submit an updated project abstract. All annual reviews for a given month are listed on the agenda and voted on/approved by the committee. All protocols expire after three years. If the project is to be continued, a de novo ACORP must be submitted to the IACUC for full review as outlined above.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The IACUC reviews the animal care and use program, and inspects all institutional animal facility areas where animals are housed and used, at least every six months. A VA semi-annual program review checklist is utilized to accomplish the program review. The VMO also conducts random PAM's during his on-site facility visits.

Current policy stipulates that the IACUC will conduct Post Approval Monitoring on at least 20% of active protocols per year. Special emphasis will be placed on protocols

that have animals assigned to USDA Category E, had past compliance issues, and/or use physical restraints. Otherwise, ACORPs in the Animal Studies Program will be randomly selected for audit by the IACUC.

The IACUC Coordinator will review the following documents for compliance, and will report any issues noted to the IACUC:

1. ACORP
2. Request for Continued Approval Forms
3. Safety Committee Approval Forms
4. Research and Development Committee Approval Forms
5. Training Documentation for all personnel

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 10**.

IACUC inspections of animal use areas provide an ongoing mechanism for ensuring that the institution maintains compliance with the applicable animal care and use policies, guidelines, and laws. At minimum, the IACUC/OB conducts bi-annual inspections of the ARF.The inspection focuses on the following areas:

1. Physical plant condition including functional space, facilities for sanitizing cages, general features of animal housing rooms, composition of floor, walls, and ceilings, lighting, heating, ventilation, and noise control

2. Laboratory animal facilities including social environment, bedding, water, food, sanitation, waste disposal, animal identification

3. Individual laboratories including the physical appearance of the work area, sanitation, use of sterile procedures, storage of anesthetic agents and drugs, record keeping, equipment used for surgery.

At least two members perform the inspection. However, no IACUC member will be excluded if he/she wants to attend a particular inspection. After the inspection, a report is prepared listing minor and significant deficiencies and a timetable for the correction of all deficiencies. The report will be reviewed by a quorum of the IACUC and signed by a majority of the quorum present. Minority views will be included in the report. The principal investigator is informed in writing of any deficiency observed by the

IACUC inspection sub-committee in his/her area and asked for a report on action taken within 30 days.
Focused inspections are performed as needed to address program issues.
No satellite or contract facilities are used.

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

The VA's ORO (Office of Research Oversight) reviewed all programs at the Bedford site in April, 2018. Concerns were raised in regard to an individual working with animals who was not listed in the personnel list on the protocol, use of a non-pharmaceutical grade substance, and veterinary visitations. All concerns were satisfactorily resolved in a timely manner and the case is closed.

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

Post approval monitoring (PAM) of IACUC-approved protocols is also performed at the Bedford VA Hospital by the VMO, to proactively identify problems and to document regulatory compliance and adherence to protocol. This PAM of approved ACORPs includes inspection of laboratories and study procedures; emphasis is on animal-related procedures, anesthesia and analgesia, surgery and euthanasia. Specific attention is paid to manipulations which have the potential to cause pain or stress. Real-time monitoring may be required by the IACUC for protocols that have prior compliance issues related to protocol execution.

Typically the VMO will visit the ARF or procedural lab and directly observe ongoing research activities. Observations will be recorded on a PAM Form. Specific areas of focus include, but are not limited to:

- Protocols and personnel
- Study procedures
- Anesthesia, surgery, analgesics and post-surgical care (if applicable)
- Euthanasia
- Record keeping
- Training
- Laboratory

Monitoring of day-to-day practices is achieved by direct observation of research personnel by the ARF Supervisor and ARF staff. ARF staff observe many routine operations performed in the ARF. Any deviations from protocol or incidents of

inappropriate animal management will be recorded by ARF staff in an "Animal Research Facility Incident Report Form"

3. **Investigating and Reporting Animal Welfare Concerns** [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

The IACUC policy titled "Reporting Deficiencies in Animal Care and Use" describes the institutional method for reporting and investigating animal welfare concerns. This policy is posted in the animal facility, in (b)(6) and on the IACUC SharePoint site, along with contact information for Research administration, Bedford VA administration, and the VA Central Veterinary Medical Office. Any individual observing an inhumane act or a deficiency in animal care is encouraged to report such practice as outlined below. To the extent possible, this institution will protect the confidentiality of those who report concerns, as well as anyone against whom allegations are directed, while allegations are under investigation.

Concerns are to be submitted in writing to a member of the IACUC. The individual(s) reporting the concern may remain anonymous. Upon receipt of a concern, the IACUC Chair will convene a meeting of the IACUC. The Veterinarian or other designated person is authorized to halt procedures which they believe do not comply with institutional policies, until the IACUC can be convened and consider the matter formally. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns. Should the IACUC determine that further investigation is required, the Chair, or another individual or subcommittee appointed by the Chair, will conduct the investigation and report back to the IACUC.

The entire committee must review the complaint, consider any voluntary testimony, and determine the corrective action necessary. The IACUC may find that:

- There was no evidence to support the concern or complaint,
- The concern or complaint was not sustained, but: a) related aspects of the animal care and use program require further review or b) other institutional programs may require review, or
- The concern or complaint was valid.

Based upon the findings, they may mandate one or more of the following corrective actions:

a. Counseling
b. Letter of Remedial Action
c. Remedial training aimed at preventing future incidents
d. Administrative hold on the ACORP
e. Monitoring by the IACUC or IACUC-appointed individuals of research, testing or training activities involving animals

4. **Disaster Planning and Emergency Preparedness** [*Guide* p. 35]
Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:
   - Identify those institutional components and personnel which would participate in the response.
   - Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

   Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The Bedford VA Disaster Plan is designed to protect animals in the event of fire, flood, severe winter storms, hurricanes, prolonged electrical power outages, or terrorism from animal rights groups. An Incident Commander is designated and placed in charge of Emergency Response Operations. The Incident Commander will usually be the senior ranking fire or police officer who reports to the emergency site, in case of fire or terrorism. The Veterinarian or Animal Facility Supervisor will be the Incident Commander in the event of flood, severe winter storms, hurricane, prolonged power outage, or other weather events. The ARF Supervisor serves as the official, initial ARF emergency responder. The Disaster Plan calls for the Facility Supervisor to report to the Incident Command Center at the onset of the crisis.

The animals, in most instances, will fare better if additional resources and critical supplies can be brought to the facility. For this reason, the facility will maintain a one-week supply of food and bedding for all species. If it is determined that research animals must be moved, the Facility Supervisor, in conjunction with the Veterinarian, must have identified a new temporary housing location before the move. The ACOS, Bedford, or authorized designee, would request the use of the (b)(6) the go-to facility in event of disaster.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

1. **Temperature and Humidity** [*Guide*, pp. 43-45]

   a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.

Note: If preferred, this information may be provided in a Table or additional Appendix.

The Metasys computer program continuously monitors temperature and humidity in the animal rooms, and records temperature and humidity readings at 15-minute intervals. It also records any alarms (high or low temperature/humidity, fan alarms, etc.). Metasys records are stored in the computers in the Engineering and ARF offices.

Each animal room has sensors which are connected to the HVAC system computer. Readings are continuously monitored by the system computer, which alerts engineering staff to changes in the environmental conditions that exceed specifications. Animal room sensors, as well as HVAC duct sensors, are connected to the HVAC alarm system, which alerts the VA Police to any malfunctions.

Individual animal housing rooms are also equipped with a thermometer/hygrometer, and temperature and humidity are maintained in accordance with the Guide recommendations. Each thermometer/hygrometer has maximum/minimum readouts, which are recorded daily by ARF staff. Daily records are maintained in a journal in the ARF office as well as monitoring sheets in each animal room.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

Temperature set points adhere to the recommended dry-bulb macroenvironmental temperatures set forth in "The Guide." The temperature set-point for mice and rats housed in the ARF is 70F. The humidity set-point is 50% RH. The HVAC system controls are designed to minimize fluctuations in temperature to +/- 3 degrees, and humidity between 30% and 70%.

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Nesting material and shelters/enrichment devices are provided for behavioral thermoregulation. Bedding in animal cages is a mixture of paper and shredded hardwood aspen and is provided in sufficient quantity for animals to build nests to enable thermoregulation.

2. Ventilation and Air Quality [*Guide*, pp. 45-47]

a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
Note: If preferred, this information may be provided in a Table or additional Appendix.

The ventilation system for all animal housing rooms is a centralized system which provides 100% fresh air. Ventilation is balanced to provide at least 10 air changes per hour. Animal rooms are generally under positive air pressure relative to the corridor. The cage wash room is under negative pressure relative to the corridor via a wall exhaust fan. The hospital Engineering Service is responsible for maintaining the ventilation system. Engineering Service utilizes an HVAC contractor to perform and document annual testing of ventilation rates and room pressure gradients.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

There are no special primary enclosures using forced ventilation.

c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

No supply air is recycled. The HVAC system supplies 100% fresh outside air.

3. Life Support Systems for Aquatic Species [*Guide*, pp. 84-87]

a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

N/A

b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

N/A

4. Noise and Vibration [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

The animal facility is located (b)(6) and is removed from laboratory and office areas. Doors to animal rooms are kept shut. The door to the cage wash area is kept shut while the machine is operating to reduce noise from the machine and air compressor.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. Primary Enclosures

Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13.**

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

The number of mice or rats housed per cage is based on floor space performance standards recommended in "The Guide." Mice are housed in polycarbonate static micro-isolator shoe box type cages, with stainless steel wire bar lids and filter tops. Current housing space meets these standards. See IACUC policy "Animal Cage Capacity and Overcrowding." No more than 5 mice weighing up to 25g each are housed per cage. Mice are monitored for weight gain, and separated if any exceed 25g in weight. Rats are housed in polycarbonate static cages with stainless steel wire bar lids.

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

There are currently no space exceptions.

2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

a. Environmental Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

The environmental enrichment program for rodents at the Bedford VAMC Animal Facility ensures that the care of rodents meets levels currently recommended by "The Guide." It is the policy of this institution to provide enrichment devices to all rodents whenever possible. Mice are provided enrichment devices such as polycarbonate shelters, tunnels, or igloos. Devices are rotated frequently to provide novelty. This allows for climbing, tunneling, nesting, and avoidance of more dominant or aggressive cage mates. See IACUC policy "Environmental Enrichment for Mice and Rats."

ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Mice are provided with cage bedding comprised of a mixture of hardwood shredded aspen and paper bedding which allows for nesting, burrowing, and thermoregulation.

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for social housing of animals.

It is institutional policy that social animals are socially housed whenever possible. Group housing is the default position. Investigators must indicate on the ACORP form whether animals will be singly housed. If animals are to be singly housed, a justification must be provided. IACUC policy allows for singly housed mice when fighting between cage mates has the potential to cause injury to an animal, or for veterinary medical reasons.

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

All animals are socially housed, unless separation is required due to fighting/aggression between cage mates, veterinary medical reasons, or due to approved experimental regimens. IACUC policy "Animal Cage Capacity and Overcrowding" permits an exception to "The Guide" in these circumstances.

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

It is desirable that social animals be housed in groups; however, when they must be housed alone, other forms of enrichment are provided to compensate for the

absence of other animals, including enrichment of the structural environment. Devices such as polycarbonate shelters, tunnels, or igloos are provided.

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Enrichment programs and social housing policies are reviewed annually at IACUC meetings. Animal care staff and the VMO observe how mice utilize enrichment devices and monitor the well-being of singly housed mice. Feedback is provided to the ARF supervisor and investigator. The investigator submits an enrichment authorization renewal form annually, which provides an opportunity to review the use of enrichment devices in their research.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]

Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

There are currently no procedures or husbandry activities that are expected to require training or habituation.

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

N/A

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

N/A

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

N/A

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

N/A

ii. Describe how food, water, and shelter are provided.

N/A

iii. Describe how animals are captured.

N/A

C. Animal Facility Management

1. Husbandry

a. Food [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

Purina, Rodent Lab Chow 5001. (b)(6) is the local distributor for Purina products and is ISO 9002 certified.

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

(b)(6)

(b)(6) The facility is used exclusively for the distribution of laboratory animal supplies. No chemicals or pesticides are stored on the premises.

Storage: Feed and bedding is stored on metal pallet racks at least 18" away from concrete floors and walls to allow for proper circulation and inspection. (b)(6) adheres to a strict inventory rotation program. All products are rotated on a first in, first out basis. Laboratory feed is received by lot number (i.e. date of manufacture) and that lot number is printed on all delivery tickets and invoices. This provides access to any background information that may be needed

and allows tracking of each bag from the time of manufacture through delivery to the customer's facility. Feed manufacture dates are carefully monitored and any product older than 180 days is disposed of properly.

(b)(6) maintains a rigid sanitation and pest control program to ensure proper vermin control. The facility is inspected and treated for pests once a month by a local pest control service, and a written report is issued.

Temperature and Humidity: (b)(6) warehouse is monitored on an hourly basis for temperature and humidity to ensure the nutritional quality of the feed is maintained for its entire shelf life. The majority of products are stored at ambient temperature, not to exceed 80°F or fall below 50°F. Deviation reports are filed for any temperatures that fall outside this range. Relative humidity averages approximately 50%. In addition, the warehouse has designated climate-controlled storage areas for temperature sensitive products. Due to the high turnover of feed, most diets leave the warehouse within a few weeks of receipt. Purina has indicated that fluctuations in temperature during that short period of time do not affect the feed. (b)(6) is a certified LabDiet dealer. Their warehouse is inspected by Purina once a year, to ensure it is within guidelines that match Purina's criteria for how LabDiet products should be stored.

Delivery Vehicles: (b)(6) vehicles are used exclusively for the delivery of animal feed and bedding. Trucks are cleaned and sanitized on a regular basis as part of the ISO 9002 program.

Limited storage of feed is done in clean storage (b)(6) in the ARF. The room is monitored for vermin daily via the use of humane mouse traps. Within animal rooms, feed bags are emptied into trash bags which line plastic barrels and covered with a lid. The mill date is placed on top of the bin to ensure that only food less than 180 days old is used. The barrels are sanitized in the cage washer each time they are emptied.

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

There are no food preparation areas.

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Several days' supply of Lab Chow is provided ad libitum on stainless steel wire cage lids.

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Food is ordered as needed from the vendor. The use of just-in-time ordering eliminates the need to store large quantities of food. This practice also virtually eliminates the possibility of food becoming outdated and lessens the chance of attracting vermin. Milling dates are checked upon arrival. Torn or damaged bags are not accepted. Food is ordered in quantities not to exceed three month's supply. Bags with older milling dates are used first, i.e., a first-in, first-out system is in place. No other provisions are made to monitor nutritional quality, bio-load, or chemical contaminants.

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

Filtered and chlorinated municipal city water is the only source of water provided to the animals. Animals drink from bottles with sipper tubes.

ii. Describe methods of quality control, including monitoring for contaminants.

The supplier of municipal drinking water, MDC Water Works, monitors for contaminants. Once per month, the hospital engineering service monitors water quality. The animal facility would be alerted to any problems with water quality by Engineering

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

No automatic water delivery systems are used.

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

A mixture of 50% hardwood Aspen shavings and 50% paper bedding is used as contact bedding. This bedding mixture has been beneficial in the past for long-term breeding and behavioral studies. It also allows for nesting, burrowing, and thermoregulation. The paper bedding provides absorption of liquids and odor control, and the shavings provide nest building material.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

There are no bulk food storage facilities in the ARF. Limited storage is done in clean storage (b)(6) in the ARF. The room is monitored for vermin daily via the use of humane mouse traps.

iii. Describe quality control procedures, including monitoring for contaminants.

Only undamaged bags of bedding are accepted. Bedding is visually checked for contaminants when transferred out of the manufacturer's bags into bedding storage containers.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

No motorized vehicles or equipment is used.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

A wet vac machine is available for accidental spills or flooding in the animal facility corridors. A small portable HEPA-filtered vacuum cleaner is used to clean the dump station filter. A chlorine dioxide sterilant vaporizer is maintained for occasional use in decontaminating animal rooms.

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Bedding in solid bottom mouse and rat cages is changed 2 times per week.

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

There are no exceptions to frequencies recommended.

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

Soiled cages are transported to the cage washing (b)(6) Here soiled bedding is dumped from the cages within a HEPA- filtered dump station, into a lined trash barrel. A dust mask and gloves are worn throughout the process.

Clean bedding is placed into sanitized cages in storage (b)(6)

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

There are no exceptions to the recommended intervals.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

Temperature indicator tapes, which change color when the designated temperature (180°) is reached, are used daily in the cage washer, during the first load washed that day. Cages are visually inspected for debris and re-washed if necessary. Microbial monitoring is performed quarterly. Cage parts and animal room surfaces are swabbed and tested with the (b)(6) (b)(6) Any Firefly tests of cages or equipment that result in readings other than zero require re-washing of the item. If needed, personnel are retrained to ensure proper sanitization procedures are being followed. After re-washing, items are swabbed and tested again to ensure that proper sanitization has been achieved.

b) Describe preventive maintenance programs for mechanical washers.

An outside vendor (b)(6) provides preventative maintenance of the cage washer three times per year. A contract is in place that provides

for routine maintenance as well as any emergency repairs that may be required.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding and refuse are removed in (b)(6) within a HEPA- filtered dump station, into a lined trash barrel. Sealed trash bags are (b)(6) (b)(6) (b)(6) (b)(6)

ii. Animal carcasses.

Animal carcasses are sealed in clear plastic bags and stored in a dedicated freezer in the animal facility. Disposal is scheduled on an as-needed basis and is done by a hazardous waste disposal company that is contracted by the hospital. Carcasses are removed from the freezer just prior to the scheduled pickup and packed in cardboard boxes that are double-bagged with biohazard bags.

g. Pest Control [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:
- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

There have been no pest problems in the facility for many years. A program for building vermin control, which follows the principles of integrated pest management, is provided by Environmental Management Service (EMS). Vermin control in the building is monitored by a Certified Pest Control Service contracted by EMS. The contractor does not use any traps or pesticides in the Research Building unless notified of a problem by EMS. Vermin control/elimination measures would be approved and overseen by the ARF Supervisor and the VMO.

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

N/A

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

The ARF Supervisor, VMO and investigator would be notified in the event EMS requested to use chemicals in the ARF. Animal rooms are never treated with pesticides when animals are present in the room. If pesticides are needed, investigators would be notified, and animals relocated.

h. Weekend and Holiday Animal Care [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

The Principal Investigator or his technician provide weekend and holiday care of the animals, checking for adequate food, water, clean bedding, condition of the animals, and proper room temperature and humidity. They would administer previously approved medical treatments, if necessary.

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

The Principal Investigator and (b)(6) echnician have many years (b)(6) is given on the protocol) experience caring for mice and rats.

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

During routine working hours (Monday thru Friday), animal-related incidents or emergencies are managed by the ARF supervisor. On weeknights, weekends, or holidays, incidents are immediately relayed to the Administrative Officer who calls the ARF supervisor or VMO. There is a backup veterinarian available, if for some reason the VMO cannot be reached. VA Police and USRO staff are provided with a copy of the Animal Facility Emergency Cascade. Contact numbers are listed in the Animal Facility Emergency Cascade, as well as posted in the ARF office, for contacting the ARF supervisor or VMO directly.

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

Cage cards are placed on all cages with the following information: Source, strain, sex, name of the investigator, phone #, protocol number, birth date and arrival date. In addition, investigators sometimes use ear tags on mice.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

Investigators are advised on the selection of animals during the protocol review process. The veterinarian is available to provide information on genetic characteristics of the inbred animals used in studies.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and sub-strain or the genetic background of all animals used in a study.

Investigators are advised on using standardized nomenclature during the protocol review process. Investigators who seek advice are referred to the Animal Models and Genetic Stocks Information Exchange Program at ILAR, Jackson Laboratory's Mouse Genome Informatics website, which includes nomenclature guidelines; and a submission form to describe spontaneous, induced, or genetically engineered mutations, to register new mouse strains, and to describe phenotypes.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Investigators who breed mice are encouraged to seek appropriate advice on their specific experiment, from the VMO or other qualified specialist. Detailed spreadsheets are kept by the technician who manages the breeding colony to maintain genetic variability.

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

Currently no breeding or generation of new genotypes is being performed. The ACORP form requires that investigators list each group of genetically modified animals and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for the protocol, they must describe any special attention needed during

routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry. Animals that become ill will be checked by the Investigator or his/her staff for behavior, appetite, and mobility. The VMO will also check all animals that exhibit unexpected clinical signs. At least daily there must be a date, initials and a brief summary of the health of the animals recorded in a log kept in the animal room. Records must be kept by the Research Staff of daily checks, and must list all supplemental support (heat, fluids, analgesics, antibiotics, etc.) that are provided to animals. The records should indicate the date and time, any problems noted (or note if there have been no changes in the animal's condition). Documentation must be kept from disease onset to endpoint.

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

At present, there are no USDA - covered species used. Bedford VA IACUC policy requires that animals be supplied by commercial vendors who maintain strict animal health programs that include monitoring for infectious agents by serologic and other screening procedures. All mice must be specific pathogen free (SPF). Rodents may be procured only from approved vendors. 'Approved vendor' status is granted to those animal suppliers that demonstrate through appropriate quality assurance measures that their animals are free of all pathogens of concern. If an Investigator wishes to import animals from another institution, that request must be approved by the ARF supervisor and VMO prior to their admittance to Quarantine in the ARF. Investigators are required to submit the two most recent health surveillance reports for the animals they wish to import.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

All vendors deliver animals directly to the ARF by a registered, temperature controlled commercial vehicle. All mice must be specific pathogen free (SPF). Animals are received

at the (b)(6) and the ARF staff brings the shipping crates into the ARF.

B. Preventive Medicine

1. Animal Biosecurity [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. that if sentinel animals are used, specific information regarding that program is to be provided below.

The methods are detailed in the SOP entitled "Health Surveillance: Facility Sentinel Program". There are currently no known mouse or rat pathogens in the ARF colonies. All animals are observed daily for signs of illness or injury by the ARF supervisor. Lab personnel also monitor colonies and any animals that may be expected to become ill due to phenotype. A sentinel health monitoring system is in place. Immune competent pathogen-free mouse and rat sentinels, received at 4 weeks of age, are maintained for at least 4 weeks before being used for serologic or parasitic testing. Two sentinel animals are housed per standard shelf rack, and placed on the bottom shelf. Dirty animal bedding from colony cages is placed in sentinel cages. On a quarterly basis, one blood sample taken from a sentinel on each rack is sent to (b)(6) for viral serology, using the (b)(6) Tracking Profile. On an annual basis, one to two live mice or rats, are sent to (b)(6) for a complete health screen (viral serology, bacteriology, parasitology and histopathology). Endoparasite examinations are done semi-annually, sampling animals randomly from every 5th cage. Fecal flotations and anal tape tests are done. Examination for ectoparasites is done in-house annually, by skin scraping sentinel animals in each room. On occasion, randomly selected animals from the investigator's colonies may be included in the health surveillance program.

b. Describe methods used to control, contain, or eliminate infectious agents.

There are currently no pathogenic infectious agents in the rodent colony. Typically, ill mice are euthanized. If the pathogen-free status of colony mice or rats were to change, the veterinarian would be consulted to determine the proper course of action for the particular agent found.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

Upon arrival, shipping cartons are inspected, and any torn, or otherwise physically compromised units are not accepted. Animals are physically inspected by ARF personnel for overall appearance and condition, health status, as well as compliance with order specifications. Mice and rats received from approved commercial vendors,

if determined to be in good health, are admitted to existing colonies. If any mice appear injured or ill they are euthanized.

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Only specific pathogen free mice or rats are ordered from commercial vendors. Once examined and deemed acceptable, animals are admitted to existing colonies. Investigators must notify the Veterinarian and ARF Supervisor in advance if animals from other institutions are required. Health surveillance reports from the exporting institution must be sent to, and approved by, the VMO prior to shipping of the animals in order to make sure that exported animals are specific pathogen free, or if not, that quarantine space is available. In some cases, animals with unwanted organisms, may be shipped to the (b)(6) for rederivation.

c. Describe the required/recommended stabilization period for each species.

After mice or rats that are ordered from commercial vendors arrive and prior to being released to investigators, they are required to acclimate for 48 hours.

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

Different species would be housed in separate rooms. SPF mice or rats are generally not separated by source. At present, mice and rats are procured from (b)(6) (b)(6) and/or from other institutions. On occasion, new stock is ordered from commercial vendors for specific colonies and is housed with that colony. Mice or rats which might be imported from other institutions would be housed in quarantine until cleared to go into the general housing population.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

Multiple species are not permitted to be housed in the same room.

c. Describe isolation procedures and related facilities for animals.

A designated isolation facility does not exist. In most cases in this program, ill animals do not require isolation, but rather can be treated in their home cages. Research

technicians or the investigators are contacted whenever an ill animal is observed. If need for isolation arose, the infrequently used (b)(6) or an empty housing room would be used, but typically, these mice or rats would be euthanized.

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

All animals are observed daily by the ARF staff or laboratory personnel, all of whom have been trained to recognize signs of illness by the veterinarian, ARF supervisor, and Investigator. The ARF Supervisor has (b)(6) experience with mice and rats. Research technicians and Investigators are urged to monitor their animals on a daily basis. All problems are verbally reported to the investigator and/or VMO. If an animal is found ill or injured, a sick animal report is completed and posted on the cage. The ARF staff will notify laboratory staff in person (or by phone if staff cannot be reached in person). In addition, the ARF Supervisor will email a sick animal notification to the Investigator and laboratory staff with information on the status of the animal, and recommendation for its care. If laboratory staff are unable to respond in the time frame recommended in the notification, the ARF supervisor will provide appropriate care to the animal, as well as notify the VMO. The VMO makes rounds twice per month and records clinical findings and any treatments on the Sick Animal Monitoring sheet in the room.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

Any animal health problems observed by ARF staff are communicated in person, by phone, or by email to the laboratory staff and Veterinarian. Urgent matters are communicated immediately in person or by phone to the laboratory staff. If laboratory staff cannot be reached or are unavailable, the ARF supervisor will contact the veterinarian by phone for guidance. If needed, the ARF supervisor will provide care to ill animals and notify laboratory staff by phone or email of the action taken.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

The health monitoring program is detailed in the SOP entitled "Health Surveillance: Facility Sentinel Program". All animals are observed daily for signs of illness or injury by the ARF supervisor. Lab personnel also monitor colonies and any animals that may be expected to become ill due to phenotype. A sentinel health monitoring system is in place. SPF animals are purchased from a commercial vendor and placed in each animal room as sentinels. Sentinel animals are evaluated quarterly for evidence of viral exposure, and semi-annually for endoparasites via anal tape test and fecal float, and annually for ectoparasites via skin scrape. Live sentinel mice, and rats if used, are sent to (b)(6) annually for comprehensive health monitoring, which includes bacteriology, parasitology, and pathology.

Veterinary approval is required for animals to be procured from unapproved sources. Investigators who wish to acquire mice or rats from vendors who are not routinely used or from other institutions must submit the two most recent negative health surveillance reports prior to the animals' arrival into Quarantine in the Animal Facility. Only specific pathogen free mice or rats will be accepted. Appropriate samples will be examined for evidence of endo- and ecto-parasites. Serum samples from sentinel mice or rats placed in Quarantine with the newly imported mice will be obtained, after 4 weeks exposure, and submitted for appropriate serologic surveys.

2. Emergency Care [*Guide*, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

The VMO is available for emergency care during and outside of regular work hours should the need arise. A backup veterinarian is available to provide care, and would be contacted by phone, if for some reason the VMO cannot be reached. Ill mice or rats are typically euthanized.

a. The ARF staff complete a yellow Sick Animal Report, attach it to the appropriate cage and notify the Principal Investigator or his/her staff. In the absence of ARF staff, the person finding the sick animal will be responsible for notifying the Principal Investigator or his/her staff.
b. When the animal is perceived to be in severe distress or pain, the ARF Supervisor or VMO will be contacted immediately, prior to completion of a sick animal report. If the ARF Supervisor or VMO determines that euthanasia of an animal is required, it will be the responsibility of the ARF staff to contact the Principal Investigator or his/her staff by phone and email, and instruct them to euthanize the animal. It is the responsibility of Investigators to provide up to date contact information to the ARF, and notify the ARF if staff absences will delay or prevent a prompt response. If the Principal Investigator or his/her staff cannot be reached, despite reasonable attempts to contact them, or are not able to euthanize the animal, appropriately trained ARF staff or the VMO may euthanize the animal.

c. The Animal Care staff will be responsible for initial examination of the animal and notifying the Investigator and/or their staff. The VMO is notified of ill animals and recommends treatment or other disposition.
d. If an animal is found to be sick or injured on a weekend or holiday, the Investigator or staff member determines disposition. Both the ARF Supervisor and VMO are available for consultation on any given case,
e. If necessary, the VMO or Animal Care staff may perform specific diagnostic procedures or recommend treatment. Research Technicians may treat animals; however, the ARF Supervisor and the VMO will oversee veterinary treatment of sick animals. Investigators and/or their staff may also be instructed to provide specific treatments.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The VMO is notified of ill animals and recommends treatment or other disposition. Investigators and/or their staff will be instructed to provide specific treatments or euthanasia. The Veterinarian (or if needed the backup veterinarian) has the authority to administer emergency treatment or perform euthanasia if necessary.

3. Clinical Record Keeping [*Guide*, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

The Bedford VAMC currently houses only mice, although rats may be used in the future. Individual records are not kept for mice or rats. Generally, mice here become ill only as would be expected with their genotype, if injured by an aggressive cage mate, or due to senility. A sick animal or dead animal report is posted on the cage. Sick Animal Logs are completed by the animal care staff or laboratory staff daily and are posted on the individual animal room doors. All observations are recorded. These records contain clinical findings, and any treatments. The VMO records observations on the sick animal log during rounds.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

Animal care staff or laboratory staff performing daily observations maintain records in the animal room. The VMO also records observations and any treatments in the Sick Animal Log. Records are subsequently filed in the ARF office and are accessible to the VMO and IACUC members.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The VMO reviews any entries made in the sick animal log since his previous visit, and records his observations on the sick animal log during rounds. He also maintains a VA-required Veterinary Visitation Log book, which records dates of his visits to the facility, animal health checks, and any other related, on-site activity.

4. Diagnostic Resources. Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

Fecal flotation and anal tape tests for endoparasites are performed semi-annually on samples obtained randomly from sentinel and colony animals. Skin scrape tests for ectoparasites are performed annually on sentinel mice from each rack.

b. Commercially provided diagnostic laboratory services.

(b)(6) conducts all necessary diagnostic laboratory testing. At present, it performs quarterly viral serologies (tracking profile) on submitted samples from sentinel mice. Sentinel mice, and rats, if they are used experimentally, are sent to (b)(6) annually for comprehensive health monitoring, which includes viral serology, bacteriology, parasitology, and pathology. (b)(6) has the capability to perform microbiology, clinical chemistry, hematology, parasitology, virology, serology and pathology analyses.

c. Necropsy facilities and histopathology capabilities.

The VMO would normally perform gross necropsies in the Procedure Room, on an as-needed basis. (b)(6) would provide histopathology services if needed. Sentinel animals are submitted to (b)(6) annually for routine necropsies and histopathology, as well as viral serology, bacteriology and parasitology.

d. Radiology and other imaging capabilities.

None.

5. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

Controlled drugs are currently not being used. Non-controlled drugs/compounds are procured through the investigator's department following the VA mandated credit card

policies and stored under the conditions recommended by the manufacturer and approved by the VA Safety department.

b. Describe record keeping procedures for controlled substances.

N/A

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

There have been no survival or non-survival surgeries in these facilities for years. The VMO would be directly involved with the investigator, in all pre-surgical planning prior to protocol submission. A detailed description of the proposed surgical procedure, and the location where it will be performed, is required in the ACORP. Once approved and prior to starting a surgical project, the PI, VMO, and ARF supervisor would meet to discuss logistics of the study.

2. Surgical Facilities [*Guide*, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

IACUC-approved procedures would be performed in a designated laboratory room in (b)(6) At present, a few mice and rats will undergo a non-survival procedure. They will be euthanized for the purpose of generating primary cultured neurons; pregnant dams

will be deeply anesthetized with isoflurane and then decapitated following embryo harvesting.

3. Surgical Procedures [*Guide*, pp. 117-118]

a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Bedford VAMC adheres to the definitions of major and minor, survival and non-survival surgery as stated in "The Guide:"

Major survival surgery –e.g., laparotomy, thoracotomy, penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transaction.

Minor survival surgery –does not expose a body cavity and causes little or no physical impairment; e.g., wound suturing, peripheral vessel cannulation.

b. How is non-survival surgery defined?

Non-survival surgery – operated animals are euthanized prior to recovery from anesthesia; clean but not aseptic technique is acceptable.

4. Aseptic Technique [*Guide*, pp. 118-119]

a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

At present, no aseptic surgical procedures are being performed. All pre-, intra-, and postoperative procedures are detailed in our SOP entitled "Guidelines on Anesthesia and Analgesia for Mice and Rats, and "Surgery and Postoperative Care - Mice and Rats". In brief:

FACILITIES
Both survival and non-survival surgery would be performed in a designated area of the laboratory or procedure room.

For survival surgeries, a designated area of the laboratory or procedure room is required. A clean, uncluttered bench top must be disinfected with 70% alcohol, chlorhexidine, or a quaternary ammonium disinfectant before use. A clean, plastic bottom absorbent drape should be used under surgical animals. The surface area should be sanitized similarly after use.

For non-survival surgeries, clean surgery is acceptable; instruments, associated equipment and gloves should be clean but not necessarily sterile.

ATTIRE
Survival surgery – clean scrubs or lab coat and sterile gloves are required. Masks are desirable but not required. Once gloved, the surgeon may touch only instruments and supplies within the sterile surgical field; gloves must be changed if inadvertently contaminated by touching non-sterile items. Gloves must be disinfected or changed between animals, when operating on multiple animals.

Non-survival surgery – Scrubs or lab coat, and clean gloves must be worn.

SURGICAL PREPARATION – SURVIVAL SURGERY

All perioperative activities must be in accordance with the IACUC approved protocol.

Animals are examined prior to surgery to assure they are in good clinical health. They are anesthetized using approved anesthetic(s). Once a surgical plane of anesthesia is reached, lubricating ointment is placed in each eye, and incision site hair removed by clipping, shaving or using a depilatory. The animal is placed on a draped, recirculating water-heating pad. The incision site is disinfected with gauze soaked in 10% chlorhexidine or with betadine swabs. A sterile, disposable drape is then placed over the animal, with the opening over the incision site.

For non-survival surgery (clean, but not sterile surgery), the surgical site should be cleaned with 70% alcohol.

SURGICAL PROCEDURES – SURVIVAL SURGERY
Aseptic technique is required for survival surgery.

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

IACUC policy requires that sterile instruments be used for each surgical procedure. Sterilization can be accomplished by steam autoclaving, dry heating, the use of liquid chemical sterilants as Alcide or Clidox, or hot bead-sterilizing.

At present, all instruments will be cold sterilized, using Clidox or Alcide. Solutions will be freshly prepared, and instruments soaked for a minimum of 6 hours.

The same instrument pack may be used for multiple animals so long as the sterile field is not contaminated, and the instruments have been disinfected between animals. Blood-contaminated scalpel blades should be replaced. Instruments used for multiple animals must be wiped with sterile saline, then disinfected by dipping in 70% alcohol, Clidox, Alcide, Betadine or Povidone and rinsed with sterile saline, or disinfected in the hot bead sterilizer.

Clean, laundered personal protective clothing (lab coats) and sterile disposable gloves will be worn.

c. Describe methods for instrument re-sterilization between serial surgeries.

N/A. No serial surgeries are being performed.

d. Indicate how effectiveness of sterilization is monitored.

Heat-sensitive autoclave tape, and spore strips, would be used to confirm the effectiveness of sterilization, when autoclaving is used.

e. Describe surgical support functions provided by the program to investigators.

Qualified scientific staff are permitted to perform specific surgical procedures and support functions. A site for surgery would be provided within the ARF or in a designated laboratory room. The VMO and the ARF Supervisor are available to provide guidance and expertise.

5. Intraoperative Monitoring [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

At present, no survival surgical procedures are performed. IACUC policy requires that animals be monitored for respiration and heart rate, and depth of anesthesia throughout the procedure.

6. Postoperative Care [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Post-operative care, including maintenance of records, would be the responsibility of the investigator. For rodent survival surgery, a surgical care card would be used on the cage and is maintained by the investigator. The ARF staff observes all animals and will provide assistance when needed.

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The ARF Supervisor conducts daily observation of animals, while the VMO observes all animals biweekly. Research staff also observes all mice on study as described in the IACUC protocol. All animals are observed for signs of injury, illness, and distress and pain. The USDA categories of pain and distress are used by the IACUC and the veterinarian. The IACUC also assesses the pain category at time of protocol review.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

IACUC Standard Operating Procedures describe guidelines for avoiding unnecessary pain or distress in research animals. Some examples would include the use of retro-orbital bleeding and avoiding the use of death as an endpoint. The IACUC may determine that pilot studies, monitored by the VMO or ARF Supervisor, are indicated in select cases. All ACORP submissions require a description of endpoint criteria, as well as a literature search for alternatives to painful procedures. Investigators are required to provide databases searched, key words, and dates of searches. They must ensure their staff are trained in observing animals used in their protocols for pain or distress. Animal care staff observe mice daily and notify the investigator and/or their staff if any signs of pain or distress are noted.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

At present, analgesia is not indicated nor provided for the species used here. A gaseous anesthetic agent, isoflurane, is used for deeply anesthetizing pregnant rodent dams, for eventual embryo harvesting. A few mice and rats will undergo this non-survival procedure.

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The VMO provides a listing in the IACUC Standard Operating Procedure of appropriate anesthetics and analgesics, with their doses. The formulary is updated as needed by the VMO. Investigators may contact the VMO if additional information is needed.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

At present, there is no monitoring, for analgesics are not in use. The use of postoperative analgesic drugs is indicated, and expected, for all survival surgical procedures, to alleviate pain and suffering. Post-operative analgesics must be used for at least the first 24 hours

after surgery. Any exception to the use of analgesic drugs in conjunction with potentially painful procedures must be approved by the IACUC and the VMO.

Postsurgical animals must have accompanying surgical records. A completed and legible" Surgery Card" must be affixed to the animal's cage. If a series of animals are operated, one card can suffice for all, however the identification of all operated animals must be on the card; an inclusive listing is acceptable.

Animals must be observed by the investigator or their staff at least once daily, to assure they are adequately performing normal bodily functions, and that wound sites are healing satisfactorily. Notations are to be made on the "Surgery Card".
Any observed postoperative complication(s) must be reported immediately to the ARF Supervisor and the investigator or their staff. The VMO is on call to assist with medical care.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

Neuromuscular-blocking drugs are not now used, nor have they been used in animals here for many years. Investigators requesting the use of a neuromuscular blocking agent are required to complete ACORP Appendix 5 and explain why its use is necessary. They must also describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain. The IACUC and veterinarian may require the amount of anesthetic be defined on the basis of results of a similar procedure using the anesthetic without a blocking agent.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

The (b)(6) anesthesia machine is newly purchased and certified by the vendor. Laboratory staff will perform routine maintenance. A service company will perform major repairs, and also perform anesthetic machine calibration at least once every three years.

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   Note: If preferred, this information may be provided in Table or additional Appendix.

The IACUC SOP on Euthanasia lists all approved means of euthanasia, in accord with the AVMA Guidelines on Euthanasia. Impending changes on carbon dioxide methodologies will be incorporated into our SOP whenever they become official. Inhalation of carbon dioxide gas is currently used to euthanize mice and rats. Euthanasia is performed in the animal facility procedure room, or in the lab in (b)(6) It cannot be performed in animal housing rooms.

Carbon dioxide chambers and chemical fume hoods are available for use for small animals. Chambers must not be overcrowded and must allow space for normal postural adjustments. When using carbon dioxide for euthanasia, animals must be placed in a sealed chamber before the introduction of CO2. They must remain in a sealed chamber for a minimum of 3 minutes from the time the gas is first administered to apparent death, and additional 1 minute to confirm death. The carbon dioxide gas must be flowing into the chamber for the entire four minutes. Larger species or a larger number of animals in the chamber may require more than 4 minutes. After a minimum of three minutes of exposure to carbon dioxide, the euthanized animals must be observed for a minimum of 10 minutes after the gas is turned off to ensure that death has occurred. A secondary, physical means of assuring euthanasia is required.

Immature (neonatal) animals are extremely tolerant of carbon dioxide and, therefore to ensure death, a secondary method of euthanasia must be used, following exposure to carbon dioxide.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

A tank of compressed CO2 gas and a sealed, polycarbonate bell jar CO2 chamber are used for euthanasia. The CO2 tank is fitted with a regulator and flowmeter, to ensure proper flow rates for euthanasia. Instructions for use of the euthanasia system are posted on the wall adjacent the chamber.

3. Describe the methods used to confirm death of an animal.

Death must be confirmed by one of the following physical methods: absence of heartbeat and/or respiration, thoracotomy or pneumothorax, exsanguination, perfusion under anesthesia, or cervical dislocation. Cervical dislocation and /or decapitation, under anesthesia, may be used for rodents, with scientific justification and IACUC approval.

Under no circumstances should the times listed in the carbon dioxide gas euthanasia policy be the only criteria for determining that death has occurred. If the time of exposure to carbon dioxide must be less than three minutes, then a secondary means of euthanasia must be employed, such as the physical methods described.

Immature (neonatal) animals are extremely tolerant of carbon dioxide and, therefore to ensure death, one of the secondary methods of euthanasia noted above must be used, following exposure to carbon dioxide.

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The Animal Research Facility (ARF) is located in the (b)(6) and consists of (b)(6) At this time the ARF Supervisor (b)(6) and provides daily oversight during the week. The PI and or their technician provide weekend and holiday checks of the facility. USRO staff check the animal facility HVAC environmental conditions daily year-round.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).

5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

1. General arrangement of the animal facilities
It is a single corridor conventional facility. Animal rooms are entered directly from a central corridor.
2. Physical relationship of the animal facilities to the research laboratories
Research laboratories are located in (b)(6)
3. Types of available animal housing spaces used
The types of space used are primarily conventional housing rooms. On occasion, quarantine space is used for animals imported from other institutions.
4. Finishes used throughout the animal facility
Floors in the animal rooms are composed of one-inch square ceramic tiles in a Portland cement base. Floors in the corridor and cage wash room are seamless vinyl. The floor in (b)(6) storage is made of one-foot square vinyl tile.

Animal room walls are composed of cement block or green board. Walls are finished with plaster and tiled. The cage wash room is cement block with plaster finish and painted with latex semi-gloss paint. Both stainless steel and plastic panels have been installed on cage wash walls to prevent moisture damage. The ceiling area in the cage wash room is not easily sanitized due to multiple exposed pipes, however it is sanitized by hand using a sponge mop and step ladder.

Ceilings are solid plaster finished with latex semi-gloss paint in all areas that house animals. With the exception of the cage wash room, all non-animal housing areas are finished with vinyl-coated acoustic ceiling tiles to allow access to mechanical systems.
5. Engineering features
The animal facility is equipped with a primary HVAC system, as well as a secondary backup system, to maintain the temperatures of the animal housing facility. The secondary backup system consists of individual air conditioning-heating units installed in each animal housing room. In the event of a failure of the primary system, the individual backup heating/ A/C units would be automatically activated by the HVAC system computer controls to help maintain temperatures for the animals until the primary system can be repaired.

Temperature and humidity is continuously monitored electronically by the HVAC system computer controls. The computer monitoring system (Metasys) automatically records

temperature and humidity sensor readings in each animal room. Each animal room has sensors which are connected to the HVAC system computer. Animal room sensors, as well as HVAC duct sensors, are connected to the HVAC alarm system. Metasys alerts the VA Police and engineering staff to any malfunctions that cause environmental conditions that exceed specifications. Metasys records can be accessed through the computer in the ARF office, as well as a computer in the Engineering office.

Metasys is currently set up to record every 15 minutes. When temperature or humidity falls outside the preset range, a visible alarm is activated in the animal facility hallway, and an alarm rings in the VA Police Office. The alarm triggers the Emergency Cascade, resulting in the VA Police contacting a representative of Engineering to evaluate the situation and ARF staff to attend to the animals if needed.

A separate spare animal housing room in the south end of the basement has its own HVAC system, and is available for use if necessary, in the event the main animal facility HVAC and/or backup system fails. The alarm for the spare animal housing room will sound in the alarm box next to (b)(6) and in the VA Police Office.

Reheat coils fail in the "off" or closed position.

The ventilation system for all animal housing rooms is a centralized system which provides 100% fresh air. Ventilation is balanced to provide at least 10 air changes per hour. Animal rooms are generally under positive air pressure relative to the corridor. The cage wash room is under negative pressure relative to the corridor via a wall exhaust fan. The hospital Engineering Service is responsible for maintaining the ventilation system. Engineering Service utilizes an HVAC contractor to perform and document annual testing of ventilation rates and room pressure gradients.

6. Security features

Security in the animal research facility (ARF) is managed in the following ways:

The facility is locked (b)(6) Keys are only given to (b)(6) (b)(6) who require access to the facility to perform their duties. The entrance door (b)(6) (b)(6) One lock is a deadbolt type with double key. One exterior door is a (b)(6)

The facility is monitored by an alarm with motion detectors and door alarms. Also, the VA police patrol the grounds at night and check buildings for any evidence of intruders.

A VA identification (ID) card system and motion detector/intrusion detection system is installed throughout the Research and Development department including the ARF. This Physical Access Control System (PACS) is controlled by VA Police. Only authorized individuals are issued access. The security system monitors access (b)(6) (b)(6) Access is monitored by VA Police who investigate all unauthorized entries.

7. Consideration for facilities with exterior windows

Not applicable. There is (b)(6)

(b)(6)

8. Storage areas for flammable or hazardous agents

No flammable agents are used. No pesticides or fuel is used. The animal facility uses cleaning/disinfection supplies such as quaternary ammonia, floor stripper, floor wax, and these are stored in the cage washing room in a closed stainless-steel cabinet.

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

No satellite or contract facilities are used. The IACUC SOP "Animals Housed/Used Outside the Animal Research Facility" describes such areas as lab space that is utilized for animal housing greater than 12 hours.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

The housing and/or use of animals outside the Animal Research Facility (ARF), is only permitted if prior approval has been granted by the VA IACUC. If any lab space is utilized for animal housing greater than 12 hours, it will be inspected semi-annually by the IACUC and must be in a secure area, in satisfactory condition, with proper equipment to provide acceptable environmental conditions. If housing takes place in such an area, the investigator is responsible for all husbandry, i.e., feeding, watering, and cage changing, and its documentation. The ARF Supervisor and the VMO will provide oversight to ensure proper animal care.

Both research (b)(6) require card access by authorized personnel, and any lab space that might be used to house animals for more than 12 hours would have a locked door.

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]
   For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:
   - Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
   - History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

Emergency power is provided for the Animal Facility HVAC system and cage washing room. In the event of a power failure, normal operation of the animal facility HVAC system and cage washer would continue through automatic transfer to power supplied by the Hospital generator. Emergency lighting is provided in the animal facility corridor. No power failures have occurred in the past three years.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

N/A. There were no animal losses or health problems resulting from system malfunctions.

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
   Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

There are no other animal use facilities.

2. **Other Animal Program Support Facilities**
   Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

A small procedure room (b)(6) is utilized for serology sample preparation, basic laboratory diagnostics such as fecal flotations and anal tape testing, and euthanasia. A quarantine room is available if necessary for receipt of mice that investigators may wish to source from a non-commercial vendor. Blood samples are sent to (b)(6) (b)(6) quarterly for routine disease surveillance.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
ACORP	Animal Component of the Research Protocol
AO	Administrative Officer
ARF	Animal Research Facility
ASISTS	Automated Safety Incident Surveillance Tracking System
ACOS/R&D	Associate Chief of Staff for Research and Development
(b)(6)	
CITI	Collaborative Institutional Training Initiative Program
CVMO	VA Central Veterinary Medical Office
ENRM VA	Edith Nourse Rogers Memorial VA
EMS	Environmental Management Service
FMS	Facilities Management Service
GRECC	Geriatric Research, Education and Clinical Center
HVAC	Heating, Ventilation, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
ID	Identification
MDC	Metropolitan District Commission
NEBAALAS	New England Branch, AALAS
OHS	Occupational Health Service
OHSP	Occupational Health and Safety Program
PACS	Physical Access Control System
PAM	Post Approval Monitoring
PRIMR	Public Responsibility in Medicine and Research
PHS	Public Health Service
RSO	Radiation Safety Officer
IBC	Research Safety Institutional Biosafety Committee
SPF	Specific Pathogen Free
SRS	Subcommittee for Research Safety
TMS	VA Learning University Talent Management System
USDA	U.S. Department of Agriculture

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
USRO	Utility Systems Repair Operator
VAMC	Veterans Administration Medical Center
VMO	Veterinary Medical Officer
VHA	Veterans Health Administration

Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cage washing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft², m², or acreage for animal housing**	**Approx. ft², m², or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
Research Service	N/A	(b)(6)		Mice, rats	158 mice 5 rats	ARF Supervisor
Satellite Housing Facilities Total (Expand in Table 17)		N/A	N/A			

Totals:	(b)(6)	
Total animal housing and support space:	**(please specify ft² or m²)**	

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

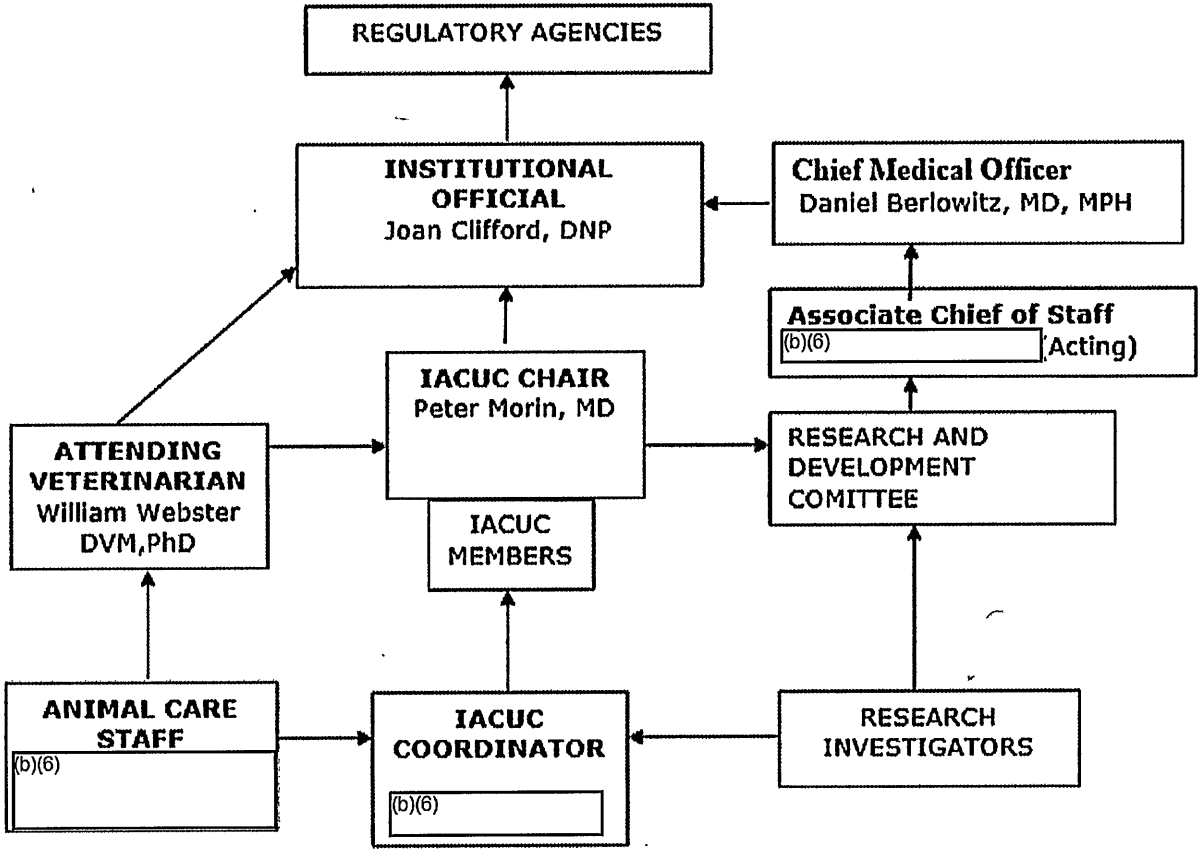
Appendix 3: Line Drawings

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

(b)(6)

Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.



Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Exploring Alzheimer Therapeutics		(b)(6)	Mice	220 4100 18	B C D						√
Exploring Alzheimer Therapeutics			Rats	110 2050 9	B C D						√

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)

Appendix 5: Animal Usage

(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

Although no USDA regulated species are currently being used, the USDA categories of pain and distress are followed. Category B mice (breeders, offspring that cannot be used because of improper genotype1 and/or gender, or other animals) are mice being maintained without any research manipulation, prior to euthanasia or transfer to another protocol. Category C procedures would involve no more than slight or momentary pain or distress, or no pain or distress. For example: observation, holding or weighing animals, ear tagging, routine injections, humane euthanasia. Category D procedures would involve pain or distress appropriately relieved by analgesia, tranquilization or anesthesia (e.g. exsanguination and/or perfusion under anesthesia).

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use
Mice	1893		
Rats	61		

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

Periodic Animal Exposure Questionnaire

Name:_____SS#: (Last 4)_____

Job Title:_____Extension:_____Bldg./Room #:_____

1. I no longer work with animals (including live animals, their tissues, waste, body fluids, carcasses or in animal rooms) at the VAMC. ☐ YES ☐ NO (if YES, skip to #4).

2. Show any **CHANGE** in animal contact within the VAMC in the past year. Write a plus (+) for continuing contact; (++) for new animal contact; (-) for animals no longer working with.

   Mice Choose an item Guinea Pigs Choose an item

   Rats Choose an item Rabbits Choose an item

   Nonhuman Primates Choose an item

   ☐ Other _____

3. Check total amount of contact time with animals in the past year (include contact with live animals, their tissues, waste, body fluids, carcasses or in animal rooms):

   ☐ More than one hour / week

   ☐ One hour or less / week

   ☐ Other (explain) _____

4. List any additions or deletions of human or animal pathogens or infectious disease agents you have worked with in the past year:

Appendix 6: Personnel Medical Evaluation Form

Additions: _____

Deletions: _____

5. List the date of your last TB screening: (Mantoux or TB Symptoms Checklist): Click here to enter a date.

6. List date of Hepatitis B, Tetanus or Rabies immunizations received this past year:

   Tetanus Click here to enter a date. Rabies Click here to enter a date. Hepatits B Click here to enter a date.

7. Check any condition(s) you have developed over the past year:

   ☐ Hay fever ☐ Asthma

   ☐ Sinusitis ☐ Other Chronic Respiratory Infection

   ☐ Allergic skin problems ☐ Eczema

   Comments:

   _____

8. Check symptoms you developed this past year and how often you have them:

Symptoms	Never	Monthly	Weekly	Daily
Watery, Itchy Eyes	☐	☐	☐	☐
Runny, Stuffy Nose	☐	☐	☐	☐
Sneezing Spells	☐	☐	☐	☐
Frequent Dry Cough	☐	☐	☐	☐
Wheezing In Chest	☐	☐	☐	☐
Rash or Hives	☐	☐	☐	☐
Shortness of Breath	☐	☐	☐	☐
Trouble Swallowing	☐	☐	☐	☐

9. Do animals cause the above symptoms? If so, please list the animals.

Appendix 6: Personnel Medical Evaluation Form

10. List any **NEW** pets you obtained in the past year and symptoms you have with them.

New Pets	Symptoms

11. List any medical problems, pregnancies, hospitalizations or surgeries this past year.

Signature of Employee:____________________ **Date:**________ **Print Name**__

Signature of Reviewer ____________________ **Print Name** _

Physical Examination: **Recommended**______ **Not Recommended**______

~~~~~~

OPT-OUT

I have been asked to provide the above information to participate in the facility Occupational Health-Animal Exposure program. I have elected not to provide information for sections 1-11, above.
I wish to opt-out of this program and prefer to consult my own healthcare professional, as needed.

☐ I am a VA employee/WOC ☐ I am not a VA employee

Signature of Employee:____________________ **Date:**________

Print Name____________________
~~~~~~

Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

Name of Member	Degree/Credentials	PHS Policy	Position Title
Voting Members			
Peter Morin	(b)(6)	Chair	(b)(6)
William Webster		Veterinarian	
(b)(6)		Alternate for (b)(6)	
(b)(6)		Alternate for (b)(6)	
		Scientist; R&D representative/ Safety representative	
		Scientist	
		Non-scientist	
		Non-affiliate	
Non-voting Members			
(b)(6)		Non scientist	(b)(6)
(b)(6)		Scientist	
(b)(6)		Non scientist	
		Consultant	

IACUC Meetings are held at least every other month, on the (b)(6) Trainings for members during meetings are designated by the Chair. Training for all animal users and care staff consists of web-based CITI and VA-specific training modules. The VMO provides training to PIs

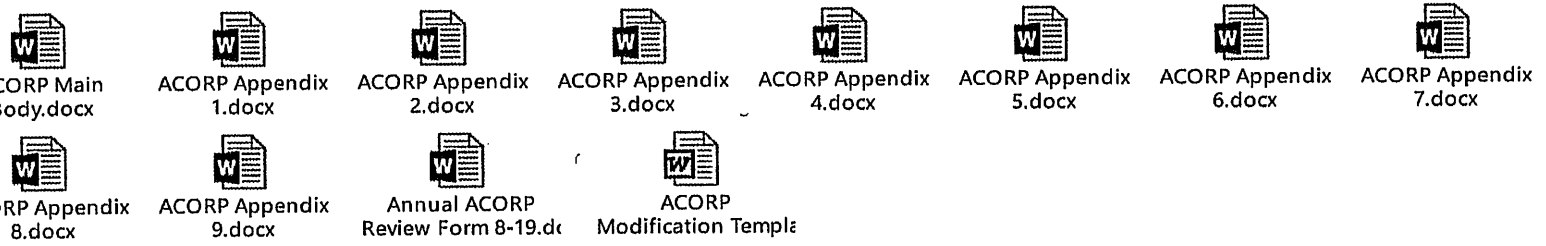
Appendix 8: IACUC/OB Minutes

IACUC Meeting Minutes July 31 2029-

IACUC minutes September 25, 2019

Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.



Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB. I.e., the Semi-Annual Program and Facilities Review

ACUP and
Semi-annual walkth

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility:	

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

The animal facility is equipped with a primary HVAC system, as well as a secondary backup system, to maintain the temperatures of the animal housing facility. The secondary backup system consists of individual air conditioning-heating units installed in each animal housing room. Reheat coils fail in the "off" or closed position to prevent overheating of animals. In the event of a failure of the primary system, the individual backup heating/ A/C units would be automatically activated by the HVAC system computer controls to help maintain temperatures for the animals until the primary system can be repaired.

The ventilation system for all animal housing rooms is a centralized system which provides 100% fresh air, with MERV filters installed on the air intake of the outdoor air handlers. Ventilation is balanced to provide at least 10 air changes per hour. Animal rooms are generally under positive air pressure relative to the corridor. The cage wash room is under negative pressure relative to the corridor via a wall exhaust fan. The hospital Engineering Service is responsible for maintaining the ventilation system. Engineering Service utilizes an HVAC contractor to perform and document annual testing of ventilation rates and room pressure gradients.

Temperature and humidity is continuously monitored electronically by the HVAC system computer controls. The computer monitoring system (Metasys) automatically records temperature and humidity sensor readings in each animal room. Each animal room has sensors

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

which are connected to the HVAC system computer. Animal room sensors, as well as HVAC duct sensors, are connected to the HVAC alarm system. Metasys alerts the VA Police and engineering staff to any malfunctions that cause environmental conditions that exceed specifications. Metasys records can be accessed through the computer in the ARF office, as well as a computer in the Engineering office.

Metasys is currently set up to record every 15 minutes. When temperature or humidity falls outside the preset range, a visible alarm is activated in the animal facility hallway, and an alarm rings in the VA Police Office. The alarm triggers the Emergency Cascade, resulting in the VA Police contacting a representative of Engineering to evaluate the situation and ARF staff to attend to the animals if needed.

A separate spare animal housing room in the south end of the basement has its own HVAC system, and is available for use if necessary, in the event the main animal facility HVAC and/or backup system fails. The alarm for the spare animal housing room will sound in the alarm box next to (b)(6) and in the VA Police Office.

The May 2019 (b)(6) air balance report for the animal facility is attached:

PDF (b)(6)

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Temporary rodent housing	70°F	Y	65-75°F (alarm)	Y	+	23.4	5/2019

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Food Prep/ Bedding Storage	N/A	N	N/A	Y	+	N/A	N/A
	Storage	70°F	Y	65-75°F (alarm)	Y	+	26	5/2019
	Storage	70°F	Y	65-75°F (alarm)	Y	+	14.4	5/2019
	Rodent Housing	70°F	Y	65-75°F (alarm)	Y	+	15.7	5/2019
	Diagnostic Lab	N/A	N	NA	Y	+	19.2	5/2019
	Storage/Rack Washing	N/A	N	NA	Y	+	15.3	5/2019
	Storage	N/A	N	NA	Y	N/A	N/A	N/A
	Storage/Freezer	N/A	N	NA	Y	-	37.3	5/2019
	Quarantine	70°F	Y	65-75°F (alarm)	Y	-	27.4	5/2019
	Staff Office	N/A	N	N/A	Y	N/A	N/A	N/A
	Rodent Housing	70°F		65-75°F (alarm)	Y	+	18.7	5/2019
	Storage	70°F	Y	65-75°F (alarm)	Y	+	16.7	5/2019
	Cage washing room	N/A	N	N/A	N	-	Variable via wall mounted exhaust fan	N/A

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

[Create additional rows by pressing TAB in the bottom-right box.]

Copy and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
N/A							

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II

Monitoring ***Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)***									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**
N/A									

Note: This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mice	(b)(6)	4-5 adults each weighing less than 25 grams	The Guide	Static microisolator polycarbonate shoe box cage. Food provided ad lib on stainless steel wire lid. Water provided ad lib in water bottles.
Rats		4-5 adults each weighing less than 400 grams		Open-topped polycarbonate cage. Food provided ad lib on stainless steel wire lid. Water provided ad lib in water bottles.

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Micro-environment				
Solid-bottom cages (static)	Mechanical washer	Twice a week	BIO-Det 750 provided by Pharmacal	Sanitization ensured by monitoring with Pharmacal Temp-Tape 180o temperature recording labels. Labels are used in the first load of the day. Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Solid-bottom cages (IVC)	N/A			
Suspended wire-bottom or slotted floor cages	N/A			
Cage lids	Mechanical washer	Every two weeks	BIO-Det 750 environmentally friendly rack & cage washing compound provided by Pharmacal	See comment above for cages
Filter tops	Mechanical washer	Every two weeks	BIO-Det 750 provided by Pharmacal	See comment above for cages
Cage racks and shelves	Hand washed with a sponge mop	Once per month	Quatricide PV-15 quaternary ammonium	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
			chloride disinfectant provided by Pharmacal	
Cage pans under suspended cages	N/A			
Play pens, floor pens, stalls, etc.	N/A			
Corrals for primates or outdoor paddocks for livestock	N/A			
Aquatic, amphibian, and reptile tanks and enclosures	N/A			
Feeders	N/A			
Watering devices	Mechanical washer	Twice a week	BIO-Det 750 provided by Pharmacal	See comment above for cages
Exercise devices and manipulanda used in environmental enrichment programs, etc.	Mechanical washer	Every two weeks	BIO-Det 750 provided by Pharmacal	See comment above for cages
Transport cages	N/A			
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	N/A			

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Euthanasia chambers	Mechanical washer	After each use	BIO-Det 750 provided by Pharmacal	See comment above for cages
Macro-Environment				
Animal Housing Rooms:				
Floors	Mopped with string mop	Daily	Quatricide PV-15	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Walls	Hand washed with a sponge mop	Monthly	Quatricide PV-15	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Ceilings	Hand washed with a sponge mop	Monthly	Quatricide PV-15	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Ducts/Pipes	Hand washed with a sponge mop	Monthly	Quatricide PV-15	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Fixtures	Hand washed with a sponge mop	Monthly	Quatricide PV-15	Sanitization ensured quarterly by monitoring with Firefly PocketSwabs.
Corridors:				
Floors	Mopped with string mop and quaternary ammonium.	Daily	Quatricide PV-15	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Walls	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Ceilings	Hand washed with a sponge mop.	Monthly	Quatricide PV-15	
Ducts/Pipes	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Fixtures	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mopped with string mop	Monthly	Quatricide PV-15	More frequently if needed
Walls	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Ceilings	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Ducts/Pipes	Hand washed with a sponge mop	Monthly	Quatricide PV-15	
Fixtures	Hand washed	Monthly	Quatricide PV-15	
Implements (note whether or not shared):				
Mops	Mechanical washer	Once per week	Quatricide PV-15	Not shared. Each room has its own.
Mop buckets	Hand washed	After each use	Quatricide PV-15	Not shared. Each room has its own.
Aquaria nets	N/A			
Other	Dustpans, brooms, brushes hand washed	Monthly	Quatricide PV-15	Not shared. Each room has its own.

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Other:				
Vehicle(s)	N/A			
Other transport equipment (list)	Carts for transporting cages, supplies, etc. within the animal facility are hand washed	After each use	Quatricide PV-15	

*Please provide chemical, not trade name.

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[*Note*: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
(b)(6)		Cage washer	Emergency "off" button; instructional signage	Guarantee 180-degree hot water rinse; temperature-sensitive tape used before first load of the day; ATP-based luminescence swabs performed quarterly
		None – hand-washing area	Limited to PPE	Visual assessment; ATP-based luminescence swabs performed quarterly

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location: (b)(6)

[*Note*: Please remove the examples provided in the Table below.]

Room Type[a]	**Light Intensity Range**	**Lighting Fixture Construction Features**[b]	**Photo-period** (hrs)[c]	**Photoperiod and Lighting Control**	**Override Mechanisms** (if applicable)
Rodent Holding Rooms	130-300 lux	Surface mounted, water resistant	12:12	Automatic via wall-mounted timer box	Mechanical on/off switch

[Create additional rows by pressing TAB in the bottom-right box.]

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc.*
[c] Note if light cycle inverted/reversed.

Repeat Location and Table as necessary for each location, including satellite housing locations.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft^2 or m^2) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes

[Create additional rows by pressing TAB in the bottom-right box.]

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
EDITH NOURSE ROGERS MEMORIAL VETERAN'S HOSPITAL, VA #518
(b)(6) Meeting Ad Hoc
(b)(6) Conference Room, (b)(6)
Attendance FY 2019

Name			Oct	Nov ^	Nov ^	Jan	Feb	Feb (b)(6)	May	June ^	July	July (b)(6)
(b)(6)	Chair (left VA Service 12/2018)	Voting member	(b)(6)									
William Webster, DVM	Veterinary Medical Officer	Voting member										
Peter Morin, MD, PhD	Scientist, Chair as of 1/2019	Voting member										
(b)(6)	Scientist, Vice Chair	Voting member										
	Scientist	Voting member										
	Non-affiliate	Voting member										
	Non-scientist	Voting member										
	Alternate- Veterinary Medical Officer	Alternate, voting member										
	Alternate for Dr. (b)(6)	Alternate, voting member										
	Non- affiliate, Community Rep.	Alternate, voting member										
	AO/R&D	ex-officio										
	Acting R&D Coordinator	ex-officio										
	RCO	Consultant										
(b)(6)	Acting ACOS/R&D	Non-Voting member										

P=present E=absent or excused *** Conference Call #present initially/left- not voting ^= ad hoc meeting

Committee voting members in attendance: 6 (see below). Members required for a quorum: 4

TOPIC	DISCUSSION	ACTIONS	TARGET DATE/ RESPONSIBILITY	STATUS
Announcements	(b)(5); (b)(6)			Complete

1

	(b)(5); (b)(6)	
Review of Committee Minutes		Complete
Old Business		
Mortality Trend Report		Complete
Sick Animal Monitoring Report		Complete
Safety Minutes Report		Complete
Post Approval Monitoring Report		Complete
Bedford-Providence MOU		Pending
New Business		
<u>New project</u> Exploring Alzheimer Therapeutics. (b)(6)		Complete
Animal Care and Use Program Review and Semi-annual walk through		Complete

			the results of this survey.	

Other Business				
Work order status	(b)(5); (b)(6)			Complete
SOP review-approved?				Complete
Adjournment				

(b)(6)

3

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
EDITH NOURSE ROGERS MEMORIAL VETERAN'S HOSPITAL, VA #518
(b)(6)

Attendance FY 2019

Name			Oct	Nov	Nov	Jan	Feb	Feb	May	June	July	July	Sept (b)(6)
(b)(6)	Chair (left VA Service 12/2018)	Voting member	(b)(6)										
William Webster, DVM	Veterinary Medical Officer	Voting member											
Peter Morin, MD, PhD	Scientist, Chair as of 1/2019	Voting member											
(b)(6)	Scientist, Vice Chair	Voting member											
	Scientist	Voting member											
	Non-affiliate	Voting member											
	Non-scientist	Voting member											
	Alternate-Veterinary Medical Officer	Alternate, voting member											
	Alternate for (b)(6)	Alternate, voting member											
	Non-affiliate, Community Rep.	Alternate, voting member											
	AO/R&D	ex-officio											
	Acting R&D Coordinator	ex-officio											
	RCO	Consultant											
(b)(6)	Acting ACOS/R&D	Non-Voting member											

P=present E=absent or excused *** Conference Call #present initially/left- not voting ^= ad hoc meeting

Committee voting members in attendance: 5 (see below). Members required for a quorum: 4

TOPIC	DISCUSSION	ACTIONS	TARGET DATE/ RESPONSIBILITY	STATUS
Announcements	(b)(5); (b)(6)			Complete

	(b)(5); (b)(6)	
Review of Committee Minutes		Complete
Old Business		
Mortality Trend Report		Complete
Sick Animal Monitoring Report		Complete
Safety Minutes Report		Complete
Post Approval Monitoring Report		Complete
Bedford-Providence MOU		Pending
Animal Care and Use Program Review and Semi-annual walk through		Complete
New Business		
ACORP Reviews and Amendments		-
ARF Disaster Plan		Complete
ARF Emergency Cascade		Complete

Other Business	(b)(5); (b)(6)	
Work order status		Complete
List of Upcoming Activities		Complete
Adjournment		

(b)(6)

ACORP Appendix 1
ADDITIONAL LOCAL INFORMATION
VERSION 4

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

ACORP APPENDIX 2
ANTIBODY PRODUCTION
VERSION 4

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) and volume (ml)				

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

   d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
   ▶

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

   ▶ ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

   ▶ ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replace-ment? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:
►

► ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
►

c. Will volume replacement be provided for blood that is collected?

► ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.
►

► ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).
►

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

► ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.
► ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
►

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
►

c. Describe how you will make sure that the animals are dead after collection of the blood:
►

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
►

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

► ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.
► ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
►

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol
►

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.
►

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

ACORP APPENDIX 3
BIOSAFETY
VERSION 4

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of <u>All</u> Materials Administered to Animals on this Protocol.** Complete the table below for <u>all</u> materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

Material (Identify the specific agent, device, strain, construct, isotope, etc.)	**Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	**Nature of Material**						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural Drug	Euthanasia agent
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

Material* (Identify the specific agent, device, strain, construct, isotope, etc.)	**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml)	**Diluent* or Vehicle***	**Route** of admin	**Frequency or duration** of admin	**Reason** for Administration and **Expected Effects**	Location of **Further Details** in this ACORP (specify "Main Body" or "App #", and identify the Item)	Administration Under **Anesthesia, sedation, or tranquilization** (Y/N)

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)

▶

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

   a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):

   ▶

   b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.

   ▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL Number of Infectious Agent	a. ABSL Number *	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?		
			Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( )**

		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ▶
Justification for applying ABSL measures that are less protective than those recommended ▶

**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

Name of Agent that Contains Recombinant Nucleic Acid	Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*	Exempt
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

ACORP Appendix 4
ANTEMORTEM SPECIMEN COLLECTION
VERSION 4

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ▶

b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
▶

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
▶

ACORP Appendix 5
SURGERY
VERSION 4

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple*
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
▶

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
▶

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

Name	Surgery #(s)	Role in Surgery

	(see Item 1)	Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery #(s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	(*)	( )*
			( )	( )*	( )*
			( )	( )*	( )*

*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol
▶

5. **Pre-operative protocol.**

a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery #(s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( )--	( )--	( )--	( )--
2	( )--	( )--	( )--	( )--
3	( )--	( )--	( )--	( )--
4	( )--	( )--	( )--	( )--

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

6. **Intra-operative management.**

a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				
	( )*				

* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.
▶

b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
▶

c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.

▶

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

   a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile Gown	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

   * Describe any "other" measures to be taken to maintain sterility during surgery.
   ▶

   b. For each surgery, describe the immediate post-operative support to be provided to the animals.

   Surgery 1 ▶

   Surgery 2 ▶

   Surgery 3 ▶

   Surgery 4 ▶

   c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)
1					
2					
3					
4					

   *For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:
   ▶

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

e. Post-operative monitoring. <u>After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency</u>.

(1) Immediate post-operative monitoring

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

(2) Post-operative monitoring after the immediate post-operative period

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

ACORP APPENDIX 6
SPECIAL HUSBANDRY AND PROCEDURES
VERSION 4

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditioning	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.
▶

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

Procedure Number (see Item 1)	Expected Potential Pain and/or Distress			
	No	Yes		
		Description	To Be Relieved	Not to Be Relieved
1	( )		( )[a]	( )[b]
2	( )		( )[a]	( )[b]
3	( )		( )[a]	( )[b]
4	( )		( )[a]	( )[b]

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		
3		
4		

ACORP APPENDIX 7
USE OF PATIENT CARE EQUIPMENT AND/OR AREAS FOR ANIMAL STUDIES
Version 4

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ▶

2. **Equipment to be Used.**

   a. Identify the equipment ▶

   b. Procedure(s) to be performed with this equipment ▶

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.
   ▶

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ▶

   b. Animal species to be studied or treated ▶

   c. Number of individual animals to be studied or treated ▶

   d. Date(s) ▶

   e. Time(s) of day ▶

   f. Procedure(s) to be performed on the animals in these areas ▶

   g. Protection and cleaning of patient care room surfaces ▶

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.
   ▶

   i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
   ▶

   j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
   ▶

   k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
   ▶

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

ACORP APPENDIX 8
USE OF EXPLOSIVE AGENT(S) WITHIN THE VMU OR IN ANIMALS
VERSION 4

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s) ▶**

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

   b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the VMU	Outside of VMU
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ▶

   d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
   ▶

   e. Period of use.
   Beginning no earlier than (date) ▶
   Ending no later than (date) ▶

   f. Animals that will be administered explosive agents:
   Species ▶

Approximate weights of individual animals ▶
Approximate number of animals ▶

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

ACORP Appendix 9

DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)*

VERSION 4

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*

▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.

▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure

▶

BODYANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Main Body
VERSION 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)►

2. VA Station Name (City) and 3-Digit Station Number►

3. Protocol Title►

4. Animal Species covered by this ACORP►

5. Funding Source(s). Check each source that applies:

►( ) Department of Veterans Affairs.
►( ) US Public Health Service (e.g. NIH).
►( ) Private or Charitable Foundation -- Identify the Foundation:
►( ) University Intramural Funds – Identify the University and Funding Component:
►( ) Private Company – Identify the Company:
►( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

(1) Title of project►

(2) If approved by the R&D Committee, give the date of approval►

b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

(1) Identify the studies described in the previously approved ACORP that have already been completed
►

(2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
►

(3) Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.
►

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ▶
(2) IACUC approval number of other protocol ▶
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ▶

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

▶( ) Research
▶( ) Teaching or Training
▶( ) Testing
▶( ) Breeding and colony management only; not for any specific research project
▶( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
▶( ) Other. Please specify▶

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
▶

C. **Experimental Design.**

1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
▶

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
▶

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
▶

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

D. **Species.** Justify the choice of species for this protocol.
▶

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name▶

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Name of Individual	Working with the VA IACUC	ORD web-based species specific course (Identify the species)	Any other training required locally (Identify the training)

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
▶

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	
	( )	( )	( )	
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

▶ ( ) Yes. Describe them ▶

▶ ( ) No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

Description (include the species and any other special features not shown elsewhere in this table)	Gender	Age/Size on Receipt	Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony)	Health Status

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

Procedures▶						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

J. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category D procedures.

▶ ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category E procedures

► ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.
►

Veterinary Care and Husbandry

L. **Veterinary Support.**

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

   Name►
   Institutional affiliation►
   email contact►

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted►
   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
►

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
►

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.
►

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

► ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
►

► ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.

►

► ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.

►

► ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

► ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )
		( )	( )
		( )	( )

► ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

► ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

► ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

► ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".

► ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas?	
	Yes	No		Yes – describe method of discreet transport	No
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE Euthanasia		
		Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production")	Collected as Part of a Surgical Procedure (Appendix 5, "Surgery")	Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection")
	( )	( )	( )	( )
	( )	( )	( )	( )
	( )	( )	( )	( )

S. **Surgery.** Does this protocol include any surgical procedure(s)?

► ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

► ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

U. **Termination or removal from the protocol.** Complete each of the following that applies:

► ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

► ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death► Method for verifying death► Secondary physical method►		( )	( )	( )
( )	Anesthetic overdose Agent► Dose► Route of administration►		( )	( )	( )
( )	Decapitation under anesthesia Agent► Dose► Route of administration►		( )	( )	( )

( )	Exsanguination under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
   ▶

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
   ▶

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

   b. Describe how the PI's staff should be contacted.
      ▶ ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)
      Name▶
      Contact Information▶

      ▶ ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	SOP (title or ID number)*	Other Items in this ACORP -- specify the Item letter(s)	Appendix 6
		Items:	( )**
		Items:	( )**
		Items:	( )**
		Items:	( )**

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.
   ▶

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years	Potentially painful or	Key words and/or search strategy used	Indicate which mandate each search addressed

		covered by the search	distressing procedures addressed		Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
   ▶

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
   ▶

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
   ▶

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
   ▶

X. **Other Regulatory Considerations.**

1. **Controlled drugs.**

   a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Pharmacy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.
►

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

► ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

► ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

► ( ) Other. Explain►

2. **Human patient care equipment or procedural areas.** Does this protocol involve use of any human patient care equipment or procedural areas?

► ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

► ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents.** Does this protocol involve use of any explosive agent?

► ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

► ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

► ( ) Appendix 1, "Additional Local Information"
► ( ) Appendix 2, "Antibody Production"
► ( ) Appendix 3, "Biosafety"
► ( ) Appendix 4, "Ante-mortem Specimen Collection"
► ( ) Appendix 5, "Surgery"
► ( ) Appendix 6, "Special Husbandry and Procedures"
► ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
► ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

► ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

Item	SOP		Approval Date
	Title	ID	
C.2.c			
M.1			
M.2			
U.4.a			
U.4.b			
V			

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

   a. **Certification by Principal Investigator(s):**

   I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

   I understand that further IACUC approval must be secured before any of the following may be implemented:

   - Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
   - Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
   - Performing any additional procedures not already described in this ACORP;
   - Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are copied here ►

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages►)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC Chair	Signature	Date

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;

   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
Name of IACUC Chair	Signature	Date

   b. **Certification by Biosafety Official.** I certify that:

   - Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";

   - The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;

   - The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

- Identification of each animal such that care for individual animals can be documented.
- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

   a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

   b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date

Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

a. **Certification by the Principal Investigator(s).**

I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of Safety/Biosafety Officer for the Facility	Signature	Date
Name of ACOS for R&D	Signature	Date

Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

MODIFICATION OF THE ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)

10-22-09

Date:

Principal Investigator:

Protocol Title:

V.A. Protocol Number:

Animal Species Covered By This ACORP (only one): mice

Type of Animal Use:
- ☐ Research
- ☐ Teaching or Training
- ☐ Testing
- ☐ Sentinel Animal Use
- ☐ Breeding and colony management only, no experimental procedures

Type of Modification: (check all that apply)		FOR OFFICE USE ONLY
☐	Increase in animal numbers	**Answer Item A.** No further action
☐	Addition of new genotype	**Answer Item A.** Scientific Review
☐	Add or modify procedures	**Answer Item B.** Safety & Scientific
☐	Add or modify test substances	**Answer Item C.** Safety & Scientific
☐	Add or delete personnel	**Answer Item D.** No further action
☐	Housing	**Answer Item E.** No further action
☐	Euthanasia	**Answer Item F.** Safety Review
☐	Surgery and Perioperative Care	**Answer Item E.** Complete Appendix 5

A. Animal Information

1. Is this a request to increase the number of animals used and/or a request to add a new genotype? *(Choose one)*
   - ☐ Increase number of animals used only. **Answer Items 1.a and 1.b.**
   - ☐ Increase number of animals and add genotype. **Answer Items 1.a and 1.b.**
   - ☐ Add new genotype only, will not increase total animal numbers. **Answer Item 1.b.**

   a. Provide animal numbers below

   b. List the strain, source, and number requested below

Strain	Source	Number requested

2. Describe the characteristics of the selected species, strain, stock, mutant, or breed that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, availability, data from previous studies, and unique anatomic or physiologic features.

3. Indicate the maximum distress/pain that the animals will experience *(A complete explanation and justification must be attached to the original protocol for category "E")*:

☐ USDA Category B (Animals that will be bred but not used for experiments)
☐ USDA Category C (Short term distress or pain with no need for pain relieving drugs)
☐ USDA Category D (Distress or pain that is relieved by appropriate drug use or euthanasia)
☐ USDA Category E (Distress or pain NOT relieved by appropriate drug use or euthanasia)

If USDA Category E, provide explanation and justification below.

4. Provide the statistical basis for the number of animals requested below (i.e., # of groups, # of animals per group, # of doses, etc.):

5. Are any of the animals requested genetically engineered or modified (e.g. transgenic, knock out, knock in)?

☐ No. You have completed the Animal Information section.
☐ Yes. Answer question 5.a.

a. Do the genetically engineered or modified animals exhibit any characteristic clinical signs or abnormal behavior related to their genotype?

☐ No.
☐ Yes. Describe here

B. Procedural Changes

1. Provide a complete description and justification for any procedural change(s) or addition(s)to the originally approved proposal for the use of animals.

2. **Location of procedures.** Complete the table below, indicating where all non-surgical procedures listed in Item B.1 will be performed. Be sure to include the sites of procedures such as radiography, fluoroscopy, computed axial tomography (CT), or magnetic resonance imaging (MRI) that may be performed outside the animal facility.

Non-surgical Procedure	Building and Room Number	Method of discreet transport, if required through non-research areas (enter N/A if not applicable)*

*Describe how animals will be transported to and from these sites. Transportation must be in accordance with the *Guide*, USDA regulations, and PHS policy in climate-controlled vehicles and sanitizable transport cages when appropriate. Transport through non-research areas must be discreet.

3. Do any procedural changes or additions cause more than momentary or slight pain or distress to the animal(s) that would not allow them to be listed in USDA Category C ?

☐ No. You have completed this section.
☐ Yes. **Answer items a., b. and c. below.**

a. Indicate the maximum distress/pain that the animals will experience *(A complete explanation and justification must be attached to the original protocol for category "E")*:

☐ USDA Category D (Pain or distress relieved by appropriate drug use)
☐ USDA Category E (Distress or pain NOT relieved by appropriate drug use)

If USDA Category E, provide explanation and justification below.

b. Describe the methods and sources used to determine that alternatives to the painful methods are not feasible or appropriate:

c. List pain level and what methods (analgesic, anesthetic, tranquilizing drug, etc., with dose/route) will be used to minimize discomfort and pain below:

Pain Level	Pain Relieving Drug	Dose	Route

C. Test Substances

1. Are test substances being added to the protocol?
☐Yes. Indicate substance(s) below and attach ACORP Appendix 3.
☐No. Proceed to Item 2.

2. Are currently approved test substances being modified ?
☐Yes. Provide a complete description of the modification below.

☐No. You have completed this section.

D. Personnel Changes

1. List any additions or deletions in personnel assigned to the study. For additions, list name, degree and status. For each person listed, describe their training and experience with experimental animals in general AND describe their experience performing the exact procedures in the species described in this ACORP.

This description must help IACUC members determine if all animal manipulations, including surgery, testing, and blood collection, are performed by individuals who are qualified to accomplish the procedures skillfully and humanely.

If newly added personnel require training, indicate who will be responsible for their training.
For deletions, list name only.

a. Additions

Name	Degree	Status (VA/WOC/NON-VA)	Experience and Role/ Responsibility
	-------	-------	
	-------	-------	

b. Deletions

Date Effective	Name

E. Describe Proposed Changes

1. Provide a complete description of the proposed changes.

F. Euthanasia

1. Provide a complete description and justification for the procedural change(s) in euthanasia from the originally approved proposal for animal use.

2. Location of procedures. Complete the table below, indicating where the euthanasia procedures listed in Item F.1 will be performed.

Euthanasia Procedure	**Building and Room Number**

3. Agents

a. Are substances being <u>added</u> to the protocol?
☐Yes. Indicate substance(s) below and attach ACORP Appendix 3.
☐No. Proceed to Item b.

b. Are currently approved substances being <u>modified</u> ?
☐Yes. Provide a complete description of the modification below.

☐No. You have completed this section.

c. Are all euthanasia methods acceptable according to the latest report of the AVMA Panel on Euthanasia? (if you are unsure how to answer, contact your veterinarian or IACUC for guidance)
☐ Yes. Proceed to item U.3.
☐ No. Justify any method that is not considered "acceptable" by the latest report of the AVMA Panel on Euthanasia, then proceed to item U.3.:

d. List the personnel who will perform euthanasia and indicate their training and experience with the method of euthanasia and the species involved. If personnel are not yet trained, indicate so and explain how they will be trained before performing euthanasia themselves.

e. If the animal care staff find an animal dead, how should the carcass be handled (e.g. refrigerated or frozen), and should a member of your staff be contacted immediately?

Certification by Principal Investigator(s).

To the best of my knowledge, I certify that the information provided in this Modification of the Animal Component of Research Protocol (ACORP) is complete and accurate. I understand that IACUC approval must be obtained before I initiate changes in my research protocol affecting the use and care of laboratory research animals. In signing this form, I am also certifying that the approved/proposed activities do not unnecessarily duplicate previous experiments.

SIGNATURES:

Name of Principal Investigator(s)	Signature	Date

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
Name of IACUC co-Chair	Signature	Date

Bedford V.A. Institutional Animal Care and Use Committee (IACUC)
ACORP Annual Review

Principal Investigator:		
Project Title:		
Protocol Number:		Approval Period: (*month/year to month/year*)

A. Species/strain	B. Number of Animals Used Since Last Annual Review	C. Total Approved (original ACORP + any new animals added from modifications)	D. Total Used Since Original Approval Date	E. Total Remaining (Col. C. minus Col. D.)

1. Project Status: (*check one*)

☐ Project is active and animal subjects are being used.

☐ Project is active but animal subjects are not being used and will not be used in the future in this project
— Delete animal use approval only – Keep project open for data analysis and manuscript preparation.

☐ Project is active but animal subjects are currently not being used and will be used in the future.

☐ Project has terminated.

2. Animal use has been in accord with the approved protocol. ☐ Yes ☐ No
If NO, submit an ACORP modification to the IACUC immediately. .

3. Changes in animal use are anticipated during the approval period : ☐ Yes ☐ No
If YES, submit an ACORP modification prior to initiating any change

Please confirm your contact information and note changes in second column.

Contact Information			Changes
Work Phone:		Home Phone:	
Email			
Office location:			

I am aware that all research projects using animals must receive prior approval by the Animal Studies Subcommittee, that any change in animal use requires prior approval by the IACUC, that continuation of approval requires annual review, that a new ACORP for each project must be reviewed and approved prior to 3 years from the date of initial approval, and that a copy of all animal related documents must be retained by the Principal Investigator for the duration of the study. At the completion of the study, all records should be turned into the IACUC. All IACUC records will be retained indefinitely. This form, together with any requested additional information, is submitted in compliance with these regulations.

_____ _____
Signature of Principal Investigator *Date*

_____ _____
IACUC Chair *Date*

(b)(6) Date _____
Acting ACOS Research and Development

Revised 8-16-19

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus here (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VHA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]* be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "►" symbols indicate **required** information:

►Date(s) of the most recent previous Review of the Program: **February 7, 2019**
►Date(s) on which this Review of the Program was conducted: **July 31, 2019**

Names of voting IACUC members who participated in the Program Review:
(The Program Review team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
Peter Morin, MD, PhD	Chair	07/31/19
(b)(6)	Vice Chair, Scientist, Liaison to SRS and R&D	07/31/19
	Non-affiliated (Community) Member,	07/31/19
William Webster, DVM	Veterinarian	07/31/19
(b)(6)	Scientist	07/31/19

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation
(b)(6)	Animal Research Facility Supervisor	07/31/19

3) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (Approved by the IACUC)
Minor Deficiency
Significant Deficiency

4) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section A), provide details in Part 2 of this form.

5) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item
† denotes a new "should" item

I. Institutional Policies and Responsibilities

	A. Shared Responsibilities	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
100†	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* ▶Name(s) of other institution(s) and the date(s) on which current formal written understanding(s) took effect: July 18, 2019		X			
	B. General IACUC Function					

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a); 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152‡	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154†	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			
155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.f)]*		X			
156†	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-.8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3)]*		X			
159	The research office provides packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			
160	A written draft of the minutes of the latest IACUC meeting is provided to all IACUC members at least 1 week before the next meeting.		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8f(2));PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d)]*		X			
163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8.f(2)(e))]*		X			
164‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D - 1.k(2)); 9 CFR (2.31(d)(1)(iv)(B);, Guide (p,5)]*		X			

165‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			
166	The IACUC does not approve any protocol that involves use of hazardous agents until the Biosafety Official and/or the Radiation Safety Official, as applicable, has signed in Item Z to confirm that the hazardous agents are properly documented in the ACORP. *[1200.07 (Appendix C-.8.c(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*	X				
168†	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*		X			
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5)]*		X			
170	IACUC approval of each protocol expires on or before the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e., tumors, infectious disease, vaccine challenges, trauma, etc.) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*		X			
173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*	X				
174‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*	X				
175	Toe-clipping is approved by the IACUC only when no other individual identification method is feasible; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*	X				
176‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30]*		X			
C. Semiannual Evaluations of the Animal Care and Use Program						

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B.1); 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B); 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8.f (1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8.f(1)(e)); PHS (IV.B); 9 CFR (2.31(c)(5); Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8.k(3))]*		X			
D. Standard Operating Procedures (SOPs)						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ►Date of latest review: **July 31, 2019**		X			
E. Addressing Concerns about Animal Welfare						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
300‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			

302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)j; 9 CFR (2.31(c)(8) and 2.31(d)(6))]*		X			
303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
305	Within 5 business days (*ORO requirement)* of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.i)]*		X			
F. Reporting to Oversight Entities						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ►Date of most recent submission: **January 25, 2019**				X	
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ►Name of the Institution that holds the PHS Assurance: **Edith Nourse Rogers Memorial Veterans Hospital** ►Effective date of most recent approved Assurance: **September 20, 2017 to September 30, 2021**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ►Date of most recent submission: **January 29, 2019**		X			

353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.e)]* ►Name of the Institution that holds the accreditation: **Edith Nourse Rogers Memorial Veterans Hospital**		X			
354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200.07 (8.l(2)(b))]* ►Date of most recent submission: February 12, 2019		X			
355	The VA Veterinary Medical Unit (VMU) annual report, which includes mice and rats, was submitted online by the specified deadline (usually January 15) within the past year. *[1200.07 (8.l(4))]*		X			
356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200.07 (Appendix E-2. c); 9CFR2.35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(h));9CFR2.35(f); PHS (IV.E)]*		X			

G. Personnel Qualifications and Training

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
400‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)).; PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			
401‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(viii); Guide (p. 15 & 115)]*		X			
402‡	All personnel are documented as being appropriately trained for their positions, and participating in formal and/or on-the-job continuing education at the prescribed intervals. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]*		X			
403†	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			

H. Occupational Health and Safety						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Occupational Health and Safety Program (OHSP)						
450‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			
451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment** – The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			
453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
The OHSP – Facilities and Procedures						
454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			
455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
The OSHP – Personal Hygiene						

457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-22)]*		X			
The OHSP – Medical Evaluation and Preventive Medicine for Personnel						
459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-.4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the VMU and for beginning work with animals. *[1200.07(Appendix C-4(2)(c))]*		X			
462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10.f(2)); Guide (p. 23)]*		X			
464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465‡	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466‡	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

II. Physical Plant

A. General						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes.*[Guide (p. 133-136)]*		X			
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

III. Operations Related to Animal Environment, Housing, and Management

A. Physical Environment						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Temperature, Humidity, and Ventilation						
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))]*. ▶ Date of latest test: **May 21, 2019 and July 29, 2019**		X			
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]*		X			
Noise						
522	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*		X			

B. Husbandry						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
General						
600‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 14)]*		X			
Population Management						
601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
Behavioral Management						
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60;63)]*		X			
603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51, 63-65)]*		X			

604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*		X			
C. Animal Procurement and Transportation						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
650‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)); Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107); 9 CFR (Part 3, Standards)]*		X			
D. Preventive Medicine						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			
701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			
E. Waste Disposal						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency

750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p. 73-74)]*		X			
F. Pest Control						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
G. Medical Supplies						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200. 07 (7.m)]*		X			
851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			
H. Emergency, After Hours, Weekend, and Holiday Animal Care						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74);* 9 CFR (2.33(b))*]*		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p. 74);* 9 CFR (2.33(b))*]*		X			
902‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			

903†	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the VMU supervisor) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

	A. Role of the Veterinarians	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
950 ‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952†	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg. 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			
953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14);USDA-APHIS Policy #3]*		X			
954 ‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123); 9 CFR (2.33(b))]*		X			
955 ‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			
	B. Surgery					

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*	X				
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*	X				
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*	X				
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*	X				
1004	Presurgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p.116)]*	X				
1005	For nonsurvival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*	X				
C. Pain, Analgesia, and Anesthesia						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡	Procedures are in place to assure anti-nociception before surgery begins. *[Guide, p 122)]*	X				
1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*	X				
1053 ‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			
D. Euthanasia						

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(xi))]*		X			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124])*		X			

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize the work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (▶Date(s) of previous evaluation: February 7, 2019).

#	Enter **M**, **S**, or **No**, for **M**inor or **S**ignificant deficiency noted in semiannual evaluation, or **No**t related to semiannual evaluation	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	M	(b)(6)	Check central humidifier for animal facility; water is dripping from the ceiling in rooms (b)(6) (b)(6)	03/29/2018	03/12/2019	348
2	M		Check HVAC. There have been several low temperature alarms for (b)(6) The current temperature is 64F but should be 70F.	02/12/2019	02/13/19	1
3	M		Check temperature of hot water supply to cage washer. The machine is not reaching 180F as required by regulation.	03/05/2019	04/15/2019	41

4	M	(b)(6)	Check exhaust fan, (b)(6) The fan stopped running and the room is hot and humid	03/11/2019	03/12/2019	1
5	M		Check HVAC for food storage room, (b)(6) The room temperature is 76-77F when it should be 70F +/- 3F.	04/01/2019	04/02/2019	1
6	M		Check HVAC for (b)(6) The temperature has been staying at 76-77F but should be 70F +/-3	05/21/2019	05/22/2019	1
7	M		Check ARF clothes washer in (b)(6) Washer is leaking and flooding the room.	06/10/2019	06/19/2019	9
8	M		Install ceiling light fixture to replace the one that was removed due to water damage.	07/30/2019	07/31/2019	1
9						
10						
11						

Table 2: Work Orders Not Yet Completed - include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below.

#	Enter **M**, **S**, or **No**, for **M**inor or **S**ignificant deficiency noted in semiannual evaluation, or **No**t related to semiannual evaluation	Work order (reference) number	Summarize work requested	Date work order was submitted	Elapsed days from submission until 07/31/19 (enter date used to calculate elapsed days)
1	M	(b)(6)	Check central HVAC system for source causing the light fixture to keep flooding, (b)(6) Partial repair has been completed. The ceiling was opened, the condensate drain, old piping and ductwork were replaced, and the ceiling was closed. The wall humidifier, however, still needs to be installed.	05/14/2018	443

2	M	(b)(6)	Check wall mounted humidifiers in rooms (b)(6) Humidifiers keep going into alarm mode causing low humidity. Rooms need to have 30-70% humidity but are getting as low as 4-9% humidity.	01/30/2019	182
3	M		Rooms (b)(6) flooded due to rainstorm. Water in the hallway coming through the wall.	04/23/2019	99
4	M		Check HVAC for (b)(6) Water is dripping from the ceiling and it now has water damage.	05/28/2019	64
5	M		Check HVAC for (b)(6) The room has been 55-61F since 5/23/19	5/31/2019	61
6	M		Patch hole in the ceiling in (b)(6) near wall mounted humidifier.	07/30/2019	1
7	M		Replace the cracked HEPA filter on the dump station /hood in room (b)(6)	08/01/2019	0
8	M		Reattach electrical device (actuator)in the temporary mouse room (b)(6)	08/01/2019	0

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
1	8	50.4
2	8	106.3

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus here (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities be completed every 6 months *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]*. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "►" symbols indicate required information:

►Date(s) of the most recent previous Inspection of the Facilities: February 7, 2019
►Date(s) on which this Inspection of the Facilities was conducted: July 31, 2019

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6)	Vice Chair, Scientist, Liaison to SRS and R&D	07/31/2019
	Non-Affiliated (Community) Member	07/31/2019
William Webster, DVM	Veterinarian	07/31/2019

Non-IACUC members who participated in the Facility Inspection:

Name	Title	Date(s) of Participation
(b)(6)	Research Compliance Officer	07/31/2019
	Animal Research Facility Supervisor	07/31/2019
John Wells, PhD	Acting ACOS Research	07/31/2019

3) The IACUC must inspect semiannually all units of the animal care and use program, including the following:
all areas within the VA animal facilities;
all spaces outside the VA animal facilities where animals are housed for > 12 hours;
any areas where any procedure is performed on animals.

Identify each unit subject to inspection (press Tab in bottom right cell to add rows to the table):

Location (name of site, building name and room number, etc.)	**Species**	**Type of Space** (e.g., VMU, satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., VMU Supervisor, PI) **of Responsible Individual**
(b)(6)			
		Food and Bedding Storage	(b)(6) ARF Supervisor
		Storage	(b)(6) ARF Supervisor
	Rat	Housing	(b)(6) ARF Supervisor
	Mouse	Housing	(b)(6) ARF Supervisor
		Procedure Room	(b)(6) ARF Supervisor
		Storage	(b)(6) ARF Supervisor
		Storage	(b)(6) ARF Supervisor
		Freezer Room	(b)(6) ARF Supervisor
		Quarantine	(b)(6) ARF Supervisor

(b)(6)		Procedure Room	(b)(6) ARF Supervisor
		Procedure Room	(b)(6) ARF Supervisor
		Cage Wash Room	(b)(6) ARF Supervisor
	Mouse	Temporary Mouse Room	(b)(6) ARF Supervisor
		Laboratory/Procedure Room	(b)(6) Lab Manager

4) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (approved by the IACUC)
Minor Deficiency
Significant Deficiency
Could Not Evaluate (during this inspection)

The last line of each section of the checklist is designated "Other Observations", for documentation of relevant observations that are not directly addressed by the checklist items.

5) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section B), provide details in Part 2 of this form.

6) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

✣ denotes a new "must" item

† denotes a new "should" item

I. Implementation of Institutional Policies

A. Performance of Work According to Protocol								
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				
1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*						X
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.						X

1153	Routine husbandry tasks observed are being performed according to documented SOPs.						X
	B. Addressing Concerns about Animal Welfare						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[1200.07 (8.k(2)); Guide (p. 24)]*		X				
	C. Occupational Health and Safety						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8.h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				
1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) ;Guide (p. 20-22)]*				X		
1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(l)); Guide (p. 20-22; 148-149)]*		X				
	D. Other observations						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1300							

II. Physical Plant

A. General							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138); 9 CFR (Part 3, Standards)]*				X		
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*		X				
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139); 9 CFR (Part 3, Standards)]*				X		
1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				
Heating, Ventilation, and Air-Conditioning (HVAC) System							
1355	Maintenance of temperature, humidity, and air pressure differentials within recommended ranges throughout the facility is documented. *[Guide (p. 43-47)]* ▶List the document(s) reviewed: Animal room log sheets		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]*		X				
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
Power & Lighting							
1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				
1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				

1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. *[Guide (p. 49-50; 142)]* For example: • Entry doors from corridors to animal housing areas are closed when not in use. • Carts, racks, and other equipment are equipped with casters. • Noisy animals are grouped in one section of the animal facility. • Sound-generating equipment is selected and located to minimize disturbance to animals		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		X				
B. Facilities for Sanitization							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress, HVAC capacity, clean storage, etc.) is available and meets program needs.*[Guide (p. 143)]*		X				
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*				X		
C. Storage Areas							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*				X		

1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality*[Guide (p. 65- 67)]*: • Feed bag stocks are rotated and used prior to expiration date or discarded. • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation.		X				
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. *[Guide (p. 69)]*	–	X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 142)]*		X				

D. Facilities for Aseptic Surgery

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*	X					
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*	X					
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20}*	X					

E. Special Facilities

(include barrier, aquatics laboratory study areas, procedure areas, imaging, core service facilities ,etc.)

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*		X				
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*		X				
1552‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p 147)]*		X				

1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
F. Ancillary Areas							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. *[Guide (p. 19; 136)]*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. *[Guide (p 136)]*		X				
G. Security							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*		X				
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				
H. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1700	Animal and procedure rooms are clear of obstacles so that personnel and equipment can move easily without impediment.				X		

III. Animal Environment, Housing, and Management

A. Physical Environment							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*				X		
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*		X				

1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				
1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*				X		
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				
B. Husbandry							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
General							
1800	Animals are appropriately separated by species and disease status. *[Guide (p.111)]*						X
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.						X
1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1.u); PHS (IV.C.1); Guide (p. 27-33)]*						X
Housing – Primary Enclosures							
1804†	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63;* the *Ag Guide]* Note: • The recommended minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide(p.58-59)]* • The recommended minimum floor space for a female mouse + litter is 51 in^2 ; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]*		X				

1805‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3.b)]*	X					
Population Management							
1809	Animal records (e.g., cage cards) include the following information, as appropriate *[Guide (p. 75-76); 9 CFR (2.35)]*: • Source of animals • Strain or stock (including genotype using standard nomenclature where applicable) • Name and contact information for PI • Protocol number • Pertinent dates (e.g., acquisition by facility, birth) • Number of individuals per group, when identified in groups • Age or weight • Gender • Individually identifiable features (e.g., markings, tattoos, ear • tags, neck chains, implanted microchips, etc.)						X
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*		X				
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*						X
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*						X
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*	X					
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*						X
Food							
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*						X

Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*						X
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p. 78, 86)]*	X					
1819‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					
Bedding							
1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*		X				
Sanitation							
1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				
C. Animal Procurement and Transportation							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3a (15)); Guide (p. 107-109); 9 CFR (Part 3, Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)); Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *[Guide (p.107)]*		X				
D. Preventive Medicine							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*						X
E. Waste Disposal							

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*				X		
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				
1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*		X				
F. Pest Control							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*		X				
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				
G. Medical Supplies							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*						X
H. Emergency, After Hours, Weekend, and Holiday Care							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X				
2101‡	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74;114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				
I. Other Observations							

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2150							

IV. Veterinary Medical Care

A. General

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				

B. Surgery

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*	X					
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*	X					
2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*	X					
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*	X					
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*	X					
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*	X					

2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*	X					
C. Pain, Distress, Analgesia and Anesthesia							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2300‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs *[Guide (p. 115)]*		X				
2301‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*	X					
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*	X					
D. Euthanasia							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				
E. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2400							

VA SEMIANNUAL EVALUATION
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Part 2 -- Table of Deficiencies and Departures

This form is for documenting the details about the observations noted in the checklists (Part 1, Sections A and B). Each deficiency, minor or significant, must be entered according to Instructions 2 and 3, below. Each "approved departure", as defined by OLAW, must be entered according to Instruction 4, below. The IACUC may also document on this form, at its discretion, other observations that are not deficiencies, and details about "deviations" that are not "departures", as defined by OLAW – these may be useful in addressing concerns raised by accreditation or regulatory agencies, or for monitoring purposes.

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Last Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities were last completed. Federal regulations require that a new evaluation be completed no later than 6 months after the last evaluation.)
   Double click in the document area to return to the main body of Form 1.

2) Enter deficiencies with corrections that were still pending on the last report. Copy onto this form each item that was reported on Form 2 of the last semiannual evaluation, for which the correction was not yet completed when the last report was signed:
   Enter the date the deficiency was first noted in a semiannual evaluation.
   If the IACUC determines that a change in the scheduled date of correction is appropriate, ~~strike out the previously approved date and~~ add the new date below it.
   Enter the actual date when the correction of the deficiency was completed. If the work is not yet complete, leave the "Actual date of completion" blank, but include in the description any relevant information about progress to date.

Note: USDA requires the IACUC to report any failure to adhere to the plan and schedule for correction that results in a significant deficiency remaining uncorrected beyond the correction date set by the IACUC. The report must be submitted in writing within 15 business days of missing the correction date set by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding the activity involved. Therefore, for the IACUC to change the correction date of a significant deficiency, it must review the justification for the change and approve a new correction date at a convened committee meeting prior to the original correction date.

3) Enter each new deficiency noted on Form 1 (Checklist), Parts A and B, of this report:
The date the deficiency was first noted.
The Part (A or B) and Item # on Form 1 to which it applies.
When applicable, indicate the location where the deficiency was noted.
A description of the specific deficiency -- Include sufficient detail for an outside observer to recognize when it has been corrected), a description of any underlying programmatic or systemic conditions that may have led to the deficiency, and a description of the plans both for correcting the deficiency and for addressing underlying factors so as to prevent recurrence. *[PHS (IV.B.3)]* Be sure to include the name of the individual who will be responsible for overseeing progress on the corrective action, on behalf of the IACUC. (The table will expand to accommodate the text entered.)
The severity of the deficiency (Minor [M] or Significant [S]), as indicated on Form 1.
The scheduled date of correction – enter the date by which the IACUC has determined that the correction should be completed.
The actual date when the correction of the deficiency was completed (leave blank if the work is not yet complete.)

4) Enter each "departure" from PHS Policy, including the provisions of the *Guide*, that has been approved by the IACUC. *[PHS (IV.B.3)]*

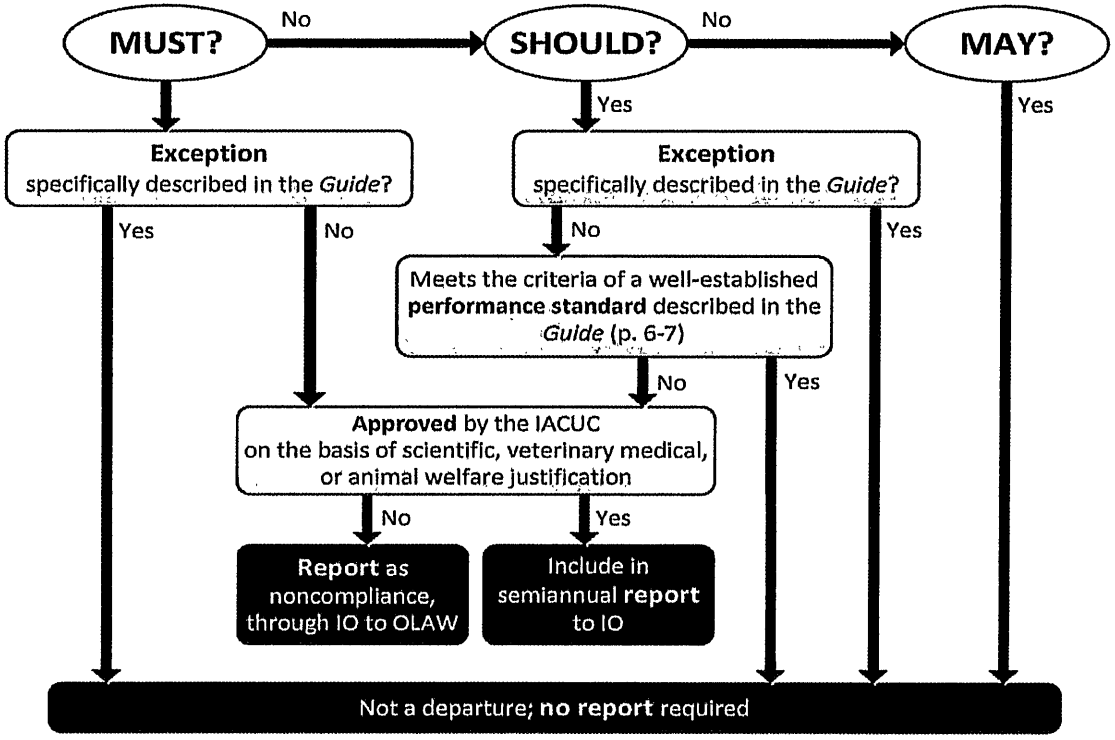
For any deviation from a general standard described in the *Guide*, the following series of test questions may be applied to determine whether the deviation is considered a "departure" by OLAW:

1. Does the Guide describe the general standard as a "May" standard? If so, this deviation from the general standard is NOT a "departure". Otherwise, for any "Should" or "Must" standard, proceed to the next question.

2. Does the Guide include an explicitly stated exception that allows for the deviation? If so, this deviation from the general standard is NOT a "departure. Otherwise, proceed to the next question.

3. Does the deviation meet a well-established performance standard for a "Should" standard, according to locally-defined and continuously monitored performance measures? If so, this deviation from the general standard is NOT a "departure". Otherwise, it IS a "departure", and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:



For approved departures that are documented in Appendix 9 of an IACUC-approved ACORP, simply attach a copy of Appendix 9. (The Official Date of Approval in the header must be included, but be sure to redact the name of the PI and the protocol number assigned by the IACUC.) Enter below the table here the total number of Appendix 9 pages attached.

For approved departures that are not documented in an Appendix 9, enter the information into this form as follows:
For "Original Date Noted", enter the date of the IACUC meeting at which the departure was reviewed and approved..
[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3) 9 CFR (2.31 (c)(3)); and Guide (p. 9]
If the departure relates to a specific item on Form 1, enter the Part (A or B) and Item # to which it applies.
If applicable, indicate the location to which the departure applies.
A description of the departure – include a summary of the grounds for granting approval for the departure.
Mark the "D" category, to indicate that the item details a departure.
Enter "N/A" in the columns for the "Scheduled Date of Correction" and the "Actual Date of Correction".

5) Press "Tab" in bottom right cell to add rows to the table.

Original Date Noted	Form 1		Location	Descriptive Details	Category			Scheduled Date of Correction	Actual Date Of Correction
	Part	Item #			M	S	D		
03/29/2018	1B	1750	(b)(6)	Check central humidifier for animal facility; water is dripping from the ceiling in rooms (b)(6) ▶ Person responsible for overseeing correction: (b)(6)	X			~~02/01/2019~~ 08/06/2019	03/12/2019

05/14/2018	1B	1750 1353	(b)(6)	There is issue with the central HVAC system stemming from the wall mounted backup humidifiers in (b)(6) The ceiling was opened, the condensate drain, old piping and ductwork were replaced, and the ceiling was closed. The wall humidifier, however, still needs to be installed. ▶Person responsible for overseeing correction: (b)(6)	X			~~02/01/2019~~ ~~08/06/2019~~ 12/31/2019	
11/27/2018 04/23/2019*	1B	1351		Water sometimes leaks into the building. Check drainage on NW corner foundation of (b)(6) rooms).* A new work order was submitted on April 23, 2019 after a rainstorm, as it is difficult for the facility to evaluate the issue when the water entry is not active. ▶Person responsible for overseeing correction: (b)(6)	X			~~08/06/2019~~ 10/31/2019	
01/30/2019	1B	1750		Check wall mounted humidifiers in rooms (b)(6) (b)(6) Humidifiers keep going into alarm mode causing low humidity. Rooms need to have 30-70% humidity but are getting as low as 4-9% humidity. The issue was evaluated. To date one of the problematic probes have been replaced. Engineering is waiting for additional parts to complete the work. ▶Person responsible for overseeing correction: (b)(6)	X			~~08/06/2019~~ 12/31/2019	

02/12/2019	1B	1750	(b)(6)	Check HVAC. There have been several low temperature alarms for (b)(6) The current temperature is 64F but should be 70F. ▶Person responsible for overseeing correction: (b)(6)	X				02/13/2019
03/05/2019	1B	1402		Because sterilizing temperatures are monitored, the ARF supervisor identified that the cage washing machine was not reaching 180F as required by regulation. This work order requested that Engineering check the temperature of hot water supply to cage washer. Engineering adjusted the steam pressure to the heater and corrected this minor deficiency. ▶Person responsible for overseeing correction: (b)(6)	X				04/15/2019
03/11/2019	1B	1750		Check exhaust fan, (b)(6) The fan stopped running and the room is hot and humid. The circuit breaker needed to be reset. ▶Person responsible for overseeing correction: (b)(6)	X				03/12/2019
04/01/2019	1B	1451		Check HVAC for food storage room, (b)(6) The room temperature is 76-77F when it should be 70F +/- 3F. Engineering changed the set point on the chiller to the summer setting ▶Person responsible for overseeing correction: (b)(6)	X				04/02/2019

05/21/2019	1B	1750	(b)(6)	Check HVAC for (b)(6) The temperature has been staying at 76-77F but should be 70F +/-3. The heating coil was adjusted to lower the temperature. ▶Person responsible for overseeing correction: (b)(6)	X			05/22/2019	05/22/2019
05/28/2019	1B	1750		Check HVAC for (b)(6). Water is dripping from the ceiling and it now has water damage. ▶Person responsible for overseeing correction: (b)(6)	X			12/31/2019	
05/31/2019	1B	1750		Check HVAC for (b)(6) The room has been 55-61F since 5/23/19 ▶Person responsible for overseeing correction: (b)(6)	X			10/31/2019	
06/10/2019	1B	1255		While PPE is supplied to ARF staff, the ARF clothes washer in (b)(6) began to leak and flood the room. Alternative options were available for sanitation of scrubs and lab coats should the need arise. A new washer has been ordered in preparation of the start of the new VA Merit funding animal study. ▶Person responsible for overseeing correction: (b)(6)	X			10/31/2019	

07/30/2019	1B	1754	(b)(6)	A dripping humidifier required removal of a light fixture while the humidifier and water damaged ceiling was being repaired. Installation of a ceiling light fixture to replace the one that was removed due to water damage is needed for proper lightening in this procedure room. ►Person responsible for overseeing correction: (b)(6)	X				07/31/2019
07/30/2019	1B	1353		Patch hole in the ceiling in (b)(6) near wall mounted humidifier where recent repair was made. ►Person responsible for overseeing correction: (b)(6)	X			10/31/2019	
08/01/2019	1B	1950		A cracked HEPA filter on the dump station /hood in room (b)(6) was identified at the time of our semi-annual program inspection. The dump station will be required once animals are housed in the ARF again. We anticipate incoming animals in late fall. ►Person responsible for overseeing correction: (b)(6)	X			10/31/2019	
08/01/2019	1B	1700		Reattach electrical device (actuator)in the temporary mouse room (b)(6) ►Person responsible for overseeing correction: (b)(6)	X			10/31/2019	

►Total number of Appendix 9 pages attached: **NONE**

VA SEMIANNUAL EVALUATION
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Part 3 – Post-Review Documentation

Instructions (The "▶" symbols indicate required information):

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities are completed.)
   Double click in the document area to return to the main body of Form 1.

2) ▶Enter the date of the most recent previous Semiannual Evaluation: **February 7, 2019**

3) Enter the names of all voting members of the IACUC, and identify the member who fills each required role on the committee, in the table in Section D, below. If any alternate members have been appointed, enter the name of each alternate member in the square brackets (e.g., "[Alt: John Smith]") below the name of each primary member for whom the alternate may serve. Only one member, the primary or the designated alternate, should sign in any one row of the table. (Press "Tab" in bottom right cell to add rows to the table.)

4) Complete Sections A-F, below.

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole. The summary should:

- Note the total number of "departures" from PHS policy, including the provisions of the *Guide*, that have been approved by the IACUC.

- Provide summary overviews of the programmatic and facility deficiencies
  - If there were no deficiencies, include a statement to this effect in the report.
  - If deficiencies were identified, evaluate the overall number and severity of the deficiencies, and what the number and severity indicate about the quality of the program and facilities (refer to the complete list provided in Part 2 – Table of Deficiencies and Departures).

- Comment on any patterns or trends suggested by the observations during this semiannual evaluation and also in the light of previous semiannual reports.

- Acknowledge any laudable aspects of the overall animal care and use program (i.e., related to the program, facility, or personnel).

- Provide a concluding paragraph that: (1) assesses the institution's overall compliance with applicable PHS Policy, the *Guide*, the AWA, and VA Policy; (2) provides recommendations to the IO; and (3) highlights any other pertinent information the IO should be made aware of.

  The Bedford VAMC Institutional Animal Care and Use Program experienced another successful and productive six months highlighted by the submission of just-in-time paperwork in September for a VA merit grant that includes an animal studies component. We anticipate an October 1, 2019 start date of the project with animals arriving before the end of the year. While a recent CRADA terminated earlier than initially anticipated, the Acting ACOS Research mentioned at a recent R&D Committee meeting that Research Administration was approached by another private company interested in contracting space in the ARF. While the Bedford VA Animal Research Facility continues to be viewed as a key component to the medical center with full support of the R&D committee and preferential use by VA investigators, it is reassuring to know that outside entities are promoting the Bedford VA as a resource.

  A number of minor facility deficiencies occurred that required work orders to be placed. Specifically, the deficiencies involved current non-animal housing or procedure rooms and mainly consisted of temperature controls and replacement of worn parts. Response times for more than the majority were appropriate. The IACUC and Research Administration is working with Engineering to close the remaining open work orders. Please note that all aspects of the facility are closely monitored with the health and well-being of all animals considered a priority.

  The IACUC previously instituted a standing meeting agenda item that recognizes all upcoming report deadlines for the year. All members will be fully aware of these deadlines and are reminded at least bi-monthly to ensure a quorum to conduct said reviews. This system has been working quite efficiently for the committee and will be valuable as the committee prepares for our institutional 2020 AAALAC re-accreditation site visit.

  Overall, the program and facility has been operating without issue in large part due to the animal care supervisor. Our program complies with the PHS Policy, the Guide, the AWA, and VA Policy. Currently, we have no specific recommendations for the IO regarding program improvements.

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8,f(1)(d)4); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

_____ Yes ___X___ No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)]*. Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program?

__X__ Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program: **Edith Nourse Rogers Memorial VA Hospital, file number** (b)(6)

Give the date of the most recent achievement of Full Accreditation:

Continued full AAALAC accreditation was awarded on June 28, 2017.

____ No. If no, describe the components that are not Fully Accredited, as indicated below.

If VA animals are housed or used at an affiliate institution that is not AAALAC accredited,

Identify the affiliate:

Give the date on which the CVMO approved this arrangement:

If VA animals are housed or used at an institution where the AAALAC accreditation status is other than Full Accreditation,

Identify the institution:

Give the current accreditation status:

Describe briefly the current status of the institution in the process of regaining full accreditation:

D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8.f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we

1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item E of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC	SIGNATURE	DATE
▶ Peter Morin, MD, PhD	Chairperson Voting Member	(b)(6)	
▶ William Webster, DVM	Attending Veterinarian Voting Member		
(b)(6)	Non-scientific (Lay) Member Voting Member		
	Non-affiliated (Community) Member Voting Member		
	Vice Chairperson, Scientist, Liaison to SRS and R&D Committees Voting Member		
	Scientist with Animal Research Experience Voting Member		
	Scientist Alternate Voting Member		
	Veterinarian Alternate Voting Member		
	Animal Research Facility Supervisor Non-Voting Member		
	Administrative Officer/R&D Non-Voting Member		
(b)(6)	Acting ACOS of Research Non-Voting Member		

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she has reviewed it. [1200.7(c)(8),(f)(1)(e)(i)].* **Note: the Director's signature only indicates awareness of the contents of the report, and does not imply agreement with the report or satisfaction with the corrective measures proposed. The report may not be altered after it has been signed by a majority of the voting IACUC membership, but any disputed items may be discussed in a cover memo.**

Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	Signature	Date
▶Joan Clifford Hospital Director	(b)(6)	

G. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to (b)(6) (b)(6) CVMO, Atlanta VA Medical Center, Research Service-151V, 1670 Clairmont Road, Decatur, GA 30033, or as an email attachment to (b)(6) @va.gov and (b)(6) @va.gov . The original must be retained for at least three years.

(b)(6)

(b)(6)

PRIVILEGED AND CONFIDENTIAL

(b)(6) **Final Report for Project** (b)(6) **-- Semiannual Testing and Certification Services**

June 5, 2019

(b)(6)

Dear (b)(6)

(b)(6)

Summary of Services

(b)(6)

(b)(6)

(b)(6)

Recommendations

(b)(5); (b)(6)

(b)

The following pages contain the field certification reports

(b)(6)

(b)(6)

(remaining pages are blank)

Document not legible